

March 21, 2018 P.M.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

In re: Bard IVC Filters,)
Products Liability Litigation)
)
) MD-15-02641-PHX-DGC
)
Sherr-Una Booker, an individual,)
) Phoenix, Arizona
Plaintiff,) March 21, 2018
v.) 12:54 p.m.
)
C.R. Bard, Inc., a New Jersey)
corporation; and Bard Peripheral) CV-16-00474-PHX-DGC
Vascular, Inc., an Arizona)
corporation,)
)
Defendants.)
)

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

JURY TRIAL - DAY 5 P.M.

(Pages 951 through 1078)

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United States District Court

March 21, 2018 P.M.

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I N D E X**TESTIMONY**

| WITNESS | Direct | Cross | Redirect | Recross |
|---------------------|---------------|--------------|-----------------|----------------|
| MICHAEL RANDALL | 960 | | | |
| DANIEL ORMS (Video) | 1003 | | | |
| ROBERT M. CARR, JR. | 1003 | | | |

E X H I B I T S

| Number | Ident | Rec'd |
|--|-------|-------|
| 422 10/24/2007 Email re Recovery G2 Filter Study (Everest) Final Study Report, TD00456, between 12/7/2005 and 7/24/2006, Protocol BPV-RC- 1332, IDE G050134 | 1039 | |
| 704 Brauer, 08/02/2017, Exhibit 1039 - Bard Everest Medical Monitor Adjudication Meeting Minutes, August 28, 2006 | 1048 | |
| 800 Carr Deposition, 12/19/2014 - Exhibit 18 - NMT RNF PDT Meeting Notes re Product Development Team, 01/13/1998 | 1015 | 1015 |
| 1033 Deford Deposition, 06/02/2016 - Exhibit 289 - Handwritten Notes on concerns about the HHE and design issues | 1019 | |
| 1222 Ganser Deposition, 10/11/2016 - Exhibit 534 - PowerPoint Presentation for a meeting to analyze EVEREST and MAUDE data and provide justifications for proposed changes to G2 filter | 963 | |
| 1452 Kaufman, 01/04/2017, Exhibit 595 - Written notes from the Recovery Filter/Clinical Panel Review with Dr. Kaufman, Dr. Anthony Venbrux, and H. Houstard, Esq. detailing issues with thrombus/clots, migration resistance, and radial force | 1016 | |

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E X H I B I T S (Continued)

| Number | Ident | Rec'd |
|---|-------|-------|
| 1517 Kessler Report - Based on the Fishbone analysis insufficient caudal anchoring is likely the root cause of caudal tilts and caudal migrations, and indirectly of penetrations and fractures." | 1039 | 1040 |
| 1578 Kessler Report ETR-06-28-29, revision 0, project #8049, Caudal Migration Test Method Development and G2 Filter Resistance Test Report, 11/27/06 | 1054 | 1057 |
| 2248 Wong deposition, 10/18/2016 - Exhibit 543 - PAT PowerPoint Presentation entitled "G2 Caudal Migration Update," dated 3/2/2006, which Wong circulated via e-mail on 3/2/2006 to several for the presentation that afternoon | 1034 | |
| 4327 Monthly Global PV Report - January 2006, date of memo, 02/10/2006 (First 7 pages only admitted) | 960 | 960 |
| 5303 G1A Recovery Filter Femoral System Design Verification and Validation Report | 1065 | 1066 |

MISCELLANEOUS NOTATIONS

| Item | Page |
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| Proceedings outside the presence of the jury | 955 |
| Sidebar conference | 1020 |

RECESSES

| | Page | Line |
|------------------------------------|------|------|
| (Recess at 2:31; resumed at 2:45.) | 1009 | 11 |

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P R O C E E D I N G S

(Court was called to order by the courtroom deputy.)

(Proceedings begin at 12:54.)

THE COURT: Thank you. Please be seated.

Mr. Condo, what are your thoughts?

12:54:53

MR. CONDO: I'm not going to take credit for all of my thoughts, Judge. This was a tougher problem than I had expected. I believe simply stated, Rule 901 is not implicated. We're not suggesting it's not an authentic Bard document.

I do think under Rule 801(d)(2) there are elements of the exhibit that are probably properly admissible as a statement against a party. But that doesn't solve the hearsay problem in other sections of the document. We have an 805 hearsay within hearsay problem because in the back half of the document, it wasn't the part that was shown to the -- shown on the monitor.

12:55:20

12:55:53

That part is probably admissible but on the back part, there are reports of various adverse events, all of which are hearsay because they are reports from doctors or hospitals or other unknown individuals being relayed to an individual, in turn, being relayed by that individual to Mr. McDermott in his preparation of this exhibit.

12:56:18

So I think at least with respect to pages eight, nine, ten, all of those are hearsay within hearsay.

THE COURT: Okay.

12:56:38

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1 Mr. Lopez? 12:56:40

2 MR. LOPEZ: Yes, Your Honor. It's easier if I stand
3 up here.

4 THE COURT: That's fine.

5 MR. LOPEZ: I'll probably have to show you the 12:56:46
6 exhibit just to give you a better sense of what it is. I mean,
7 it's clearly -- they recognize there's been a foundation laid.
8 It's clearly a business record. I mean, the Bard Peripheral
9 Vascular logo all over it. And I think more importantly, Your
10 Honor, the cover email is between the CEO and the CFO of one 12:57:04
11 defendant and the president of another defendant. It's
12 clearly -- and it does contain a ton of admissions under
13 801(d)(2), (C) and (D). It was made by a person by whom the
14 party authorized to make this.

15 THE COURT: Let me just save some time. I don't 12:57:29
16 think the defendants are disputing that the memo written by the
17 officer satisfies 801(d)(2) --

18 MR. LOPEZ: The entire document --

19 THE COURT: -- so the question is what about those
20 last three pages that the defendants assert are hearsay within 12:57:42
21 hearsay?

22 MR. LOPEZ: The entire document is a monthly global
23 pharmacovigilance report between the CEO and CFO of the company
24 from the president and attached to it is a summary of the
25 adverse events as they relate to the filter involved in this 12:58:05

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1 case. We have this knowledge now with the CEO and COO of the
2 corporate entity and the president of the entity and this
3 notice to them which suggests -- I mean, a lot of things but
4 this is their report that they get on a monthly basis. It's
5 called a monthly global PV report. It's about this.

12:58:09

12:58:27

6 THE COURT: All right. Because we only have one
7 minute left, clearly I'm going to need to look at the document
8 to see whether I agree with Mr. Condo's assertion that pages
9 eight, nine, and ten are hearsay within hearsay. So can
10 somebody provide me with a copy?

12:58:45

11 MR. LOPEZ: We can, Your Honor. On that point
12 hearsay within hearsay, it still satisfies all the exceptions
13 under 801(d)(2).

14 THE COURT: If it's hearsay within hearsay, you have
15 to have an exception for the second hearsay, that is, the
16 statements in pages eight, nine, and ten. So that's the
17 argument that is being made by the defendant.

12:58:57

18 MR. LOPEZ: I mean, even if it doesn't satisfy under
19 the non-hearsay section, Your Honor, there's clearly an
20 exception to the hearsay rule here. This is an official
21 business record. This is a monthly report.

12:59:19

22 THE COURT: To satisfy 803(6) you've got to lay
23 foundation through a custodian which you haven't done. This
24 witness cannot lay the foundation for 803(6) that it was made
25 at or about the time, that it was kept in the ordinary course

12:59:35

United States District Court

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1 of business, et cetera. So you might be able to do it through
2 another witness but not through this witness. So 803(6) isn't
3 your answer now.

4 It seems to me 801(d)(2)(A) applies to the first
5 seven pages and it sounds like defendants are agreeing. And
6 the question is, do you -- number one, do you agree that the
7 last three pages are hearsay within hearsay? And, number two,
8 if they are, what is the exception for that separate hearsay?

9 MR. LOPEZ: All right.

10 THE COURT: But I'm happy to look at it to see if I
11 agree with the proposition that it's hearsay within hearsay and
12 I can do that while we're continuing with Mr. Randall.

13 MR. LOPEZ: I'll just say it's been produced to us.
14 It has been used at depositions. These come out every month
15 and it's a business record.

16 THE COURT: But that's 803(6) and you have to meet
17 the requirements of that rule which you can't do through this
18 witness. So I don't think that solves the problem now.

19 MR. LOPEZ: Well, okay. I think it's
20 self-authenticating.

21 THE COURT: Still it has to satisfy a hearsay
22 exception and they are conceding it's self-authenticating for
23 purposes of Rule 901, but that doesn't satisfy 803(6) and it
24 doesn't satisfy hearsay within hearsay if the last three pages
25 are separate hearsay.

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1 MR. LOPEZ: All right. 01:00:50

2 THE COURT: Is there a copy that I can look at from
3 somebody?

4 MR. LOPEZ: Yes.

5 THE COURT: Let's go ahead and have Mr. Randall come 01:00:58
6 in and get the jury in.

7 MR. LOPEZ: And, Your Honor, what portion of this can
8 I use at least right now?

9 THE COURT: Well, Mr. Condo, you're not objecting to
10 the admission of the first seven pages; is that right? 01:01:12

11 MR. CONDO: I believe that's -- let me just check the
12 page number and make sure, Judge, but I think that's -- yes.
13 We're not objecting to the first seven pages of the exhibit.

14 THE COURT: Okay. So I will admit pages one through
15 seven of this exhibit and we'll address the other three pages 01:01:29
16 later.

17 (Jury enters at 1:02.)

18 THE COURT: All right. Please be seated.

19 Mr. Lopez, what is the number of that exhibit? Was
20 that 4327? 01:02:44

21 MR. LOPEZ: 4327.

22 THE COURT: All right. Ladies and gentlemen, there
23 was a motion to admit Exhibit 4327. We've had a discussion
24 while you were out. I'm going to admit the first seven pages
25 of that exhibit at this time. 01:02:57

United States District Court

MICHAEL RANDALL - Direct

1 (Exhibit Number 4327, first 7 pages only, was
2 admitted into evidence.)

01:02:58

3 MR. LOPEZ: Thank you, Your Honor.

4 THE COURT: And when one of you gets a copy, go ahead
5 and bring it up to Traci. I'll go ahead and look at the rest
6 of it.

01:03:05

7 MR. LOPEZ: Will do.

8 (MICHAEL RANDALL, a witness herein, was previously
9 duly sworn or affirmed.)

10 MR. LOPEZ: Let's go ahead and deal with 4237. And
11 at this time, Your Honor, I'll offer those seven -- those first
12 seven stipulated pages.

01:03:13

13 THE COURT: All right. Those are admitted.

14 MR. LOPEZ: Can we publish this to the jury, Your
15 Honor?

01:03:48

16 THE COURT: Yes, you may.

17 **DIRECT EXAMINATION** (Continued)

18 BY MR. LOPEZ:

19 Q. Mr. Randall, I know you were not at Bard yet in February
20 of 2006 but I would like to show you page five of Exhibit 4327,
21 okay?

01:03:57

22 A. Okay.

23 Q. This is more just to orient us in time. This was in
24 February of 2006; correct?

25 A. Correct, that's the date of it.

01:04:20

United States District Court

MICHAEL RANDALL - Direct

1 Q. What is a global PV report?

01:04:22

2 A. I'm not sure what this report is.

3 Q. You've never seen a global PV report?

4 A. No.

5 Q. Does PV stand for pharmacovigilence?

01:04:35

6 A. I don't know. I'm not sure what it stands for. Maybe
7 peripheral vascular? I'm not sure.

8 MR. LOPEZ: Let's look at that box that is
9 highlighted, Greg, please, call that out.

10 BY MR. LOPEZ:

01:04:59

11 Q. So on February 10 of 2006, the president of Bard
12 Peripheral Vascular Division of C.R. Bard to the CEO and
13 COO received this, right, according to this document?

14 A. Yes.

15 Q. And this is because the G2 with caudal improvements. Do
16 you see that?

01:05:15

17 A. Yes.

18 Q. And this project was initiated to modify the G2 filter to
19 minimize caudal migration. Do you see that bullet point?

20 A. Yes.

01:05:28

21 Q. Is that a redesign of the G2?

22 A. I'm not sure what this project is.

23 Q. Let me ask you, if you're modifying something to minimize
24 the risk, are you agreeing that the device is being redesigned?

25 A. That is different than redesign so modification to a

01:05:43

United States District Court

MICHAEL RANDALL - Direct

1 design would be considered.

01:05:46

2 Q. And then it states in bold point number two: Caudal
3 migration failure investigation under way to determine the
4 design and physiological root causes.

5 Do you see that, sir?

01:05:56

6 A. Yes, I see that.

7 Q. And the team is developing a test method for evaluating
8 caudal migration resistance.

9 Do you see that?

10 A. Yes.

01:06:07

11 Q. The device is on the market already; right?

12 A. G2, yes, is on the market.

13 Q. And then this was in January of '06 and sometime in I
14 think it was June of 2008 you're on a team that is still
15 discussing these modifications and design changes to the exact
16 same device; correct?

01:06:22

17 A. Yeah, February 6 and -- in 2008, correct, that's one of
18 the things we were discussing.

19 Q. All right.

20 MR. LOPEZ: Greg, if we go backwards to the second
21 page of this document.

01:06:46

22 Q. Do you see this is the key product line trends? Do you
23 see that, sir, what I've highlighted in yellow?

24 A. Yes.

25 Q. And those filters, does that mean IVC filters? Sir?

01:07:03

United States District Court

MICHAEL RANDALL - Direct

1 A. I'm reading. It's the first time I'm seeing the document.

01:07:11

2 Yep, it says filters.

3 Q. Okay. They didn't give you -- this was in the packet that

4 was given to them yesterday. You didn't look at this

5 particular document before today?

01:07:21

6 A. Is this still the memo from the president of --

7 Q. From Mr. McDermott to Mr. Ring.

8 A. No, I haven't seen this.

9 Q. So it's pretty clear here that as of this time, the

10 company's top executives know that they are continuing to sell

01:07:40

11 the G2 device; right?

12 MR. CONDO: Objection. 602.

13 THE COURT: Sustained.

14 MR. LOPEZ: All right. Let's go back to the exhibit

15 we had in front of the jury before we broke for lunch and that

01:07:59

16 was 1222.

17 Q. If my timing is correct, you had already successfully gone

18 to FDA and cleared the G2 by putting a hook at the top; right?

19 A. Timing correct in terms of what?

20 Q. With respect to this meeting. In other words, you could

01:08:30

21 now move on to whatever you were going to talk about next about

22 the G2.

23 A. Yes. We had approval on G2 Express or G2X.

24 Q. And let's look at the next slide after where there was

25 once your picture; correct?

01:08:53

United States District Court

MICHAEL RANDALL - Direct

1 THE COURT: Do you want this displayed? 01:08:55

2 MR. LOPEZ: Oh, yes, Your Honor. I do. It was
3 displayed when we left. I'm sorry. Please display to the
4 jury. I need a bigger sign.

5 Next slide. Slide number three. 01:09:20

6 BY MR. LOPEZ:

7 Q. We talked about that right before we broke; correct?

8 A. Correct.

9 Q. And then the next page, this is the agenda for the
10 meeting; correct? 01:09:31

11 A. I don't know if this is the final agenda but this is --
12 because this is a draft but I think those would be discussed.

13 Q. Well, it's the only agenda that you've seen about this
14 meeting; correct?

15 A. From the document provided to me, correct. 01:09:45

16 Q. And were you provided with a different agenda that is
17 different than the agenda that is being displayed right now?

18 A. Not a document that was provided to me.

19 Q. And by the way, yesterday there was some discussion about
20 just a few documents that were provided to one of our experts 01:10:02

21 and they were hundreds and hundreds of thousands of other
22 documents that the company had. Did you go through any of
23 those documents before you showed up here today that might
24 counter any of the evidence that has been introduced into this
25 trial thus far? 01:10:19

United States District Court

MICHAEL RANDALL - Direct

1 A. I'm not even sure how to answer that. What does that
2 mean?

01:10:23

3 Q. In other words, did you go through a bunch of documents,
4 thousands and thousands of documents for the purpose of putting
5 a different perspective on the evidence that has already been
6 introduced in this case?

01:10:34

7 MR. CONDO: Objection, Your Honor. Both
8 argumentative and there's no foundation.

9 THE COURT: Overruled.

10 THE WITNESS: I've reviewed a bunch of documents that
11 were provided. I'm not sure. Does that answer your question?

01:10:46

12 BY MR. LOPEZ:

13 Q. I think it does. I think it was no, you didn't do that.
14 You just looked at the stuff that was given to you by your
15 lawyer; right?

01:11:00

16 A. Yes. Yes.

17 Q. So I want to make sure we're clear about this. The
18 documents that you were given to prepare for your deposition
19 were chosen by the lawyers representing Ms. Booker that were
20 then given to you?

01:11:13

21 A. Correct.

22 Q. And that's all you thought you needed to review for
23 purposes of preparing yourself to give important factual honest
24 testimony in this case?

25 A. Yes. That's all that was provided to me.

01:11:25

United States District Court

MICHAEL RANDALL - Direct

1 MR. LOPEZ: All right. Can we go to the next page,
2 please, Greg.

3 BY MR. LOPEZ:

4 Q. And these are the complication definitions and we've
5 talked about these before about migration, tilt, penetration.
6 Do you see those definitions?

7 A. Yes.

8 Q. Let's look at the next page. Now, the jury hasn't seen
9 the EVEREST data yet or the data. They saw some yesterday but
10 is this the first time that you were familiarizing yourself
11 with the EVEREST trial?

12 A. Yes.

13 Q. And you see this is the complication that is within the
14 EVEREST trial; correct?

15 A. Correct.

16 Q. And the people that you identified earlier were discussing
17 this at the meeting; right?

18 A. Correct.

19 Q. Did you prepare this particular slide, slide six of this
20 exhibit?

21 A. No, I did not prepare this PowerPoint at all.

22 Q. I assume you understand what it depicts?

23 A. Yes.

24 Q. And this reveals to us that the total patients that had
25 follow-up in the EVEREST trial were 83; correct? Is that

United States District Court

MICHAEL RANDALL - Direct

1 right?

01:12:43

2 A. That's what it says down here at the bottom.

3 Q. And then we have three circles, one for tilt, one for
4 penetration and one for caudal migration. Do you see that?

5 A. Yes.

01:12:54

6 Q. And explain to the jury if you will the significance of
7 those three circles intersecting?

8 A. So what this is it's called a Venn diagram and a Venn
9 diagram is used to try and see if there's any relation between
10 different events or in this case complications. So the circles
11 that have overlap. If there's a number that is inside, say,
12 the tilt circle, for instance, that two versus that penetration
13 that is inside of that circle, it meant that that particular
14 filter had tilt and penetration. So it's not just one
15 complication. There was two noted on that. So it's used to
16 just try and see relationships.

01:13:13

01:13:41

17 Q. For example, if you look at the four that is between the
18 blue, the yellow and the orange -- it looks orange to me. Do
19 you see the four?

20 A. The four, yes.

01:14:00

21 Q. That means that there were four patients who had caudal
22 migration, tilt, and penetration; correct?

23 A. No. They had caudal migration and tilt. Because it's not
24 in the circle for penetration.

25 Q. Oh. You're right. So four patients had both caudal

01:14:18

MICHAEL RANDALL - Direct

1 migration and tilt; correct?

01:14:22

2 A. Correct.

3 Q. And if you look at the three in the middle of this Venn
4 diagram, it has an asterisk by it. Do you see that?

5 A. Yes.

01:14:34

6 Q. Now that one does say that there were three patients out
7 of 83 who had tilt, caudal migration and penetration; true?

8 A. Correct.

9 Q. And there was one patient out of 83 in this trial that had
10 all three of those things and a fracture of an arm and a leg;
11 true?

01:14:55

12 A. Correct.

13 Q. And by the way, when did the data of the EVEREST study
14 become available for the company to see what is depicted in
15 this exhibit?

01:15:12

16 A. I'm not sure. I'm assuming when it got approved. I
17 wasn't part of that project so I don't know.

18 Q. Do you know if that happened before June of 2007 when Ms.
19 Booker received her G2 filter?

20 A. That the data got released?

01:15:34

21 Q. That the company was aware of the data, the clinical data,
22 from the EVEREST trial.

23 A. I don't know.

24 Q. Okay.

25 MR. LOPEZ: Let's go to slide eight.

01:15:49

United States District Court

MICHAEL RANDALL - Direct

1 BY MR. LOPEZ:

01:15:56

2 Q. And I assume when people are sitting around talking about
3 this data that they have done a lot of research and you're
4 getting accurate data about what is being reported; true? We
5 can assume that?

01:16:04

6 A. I'm sorry. Can you say that again?

7 Q. We can assume this data is accurate because it's
8 well-researched and a lot of people contributed to what's in
9 this particular document. Is that true?

10 A. Yeah. I mean, it's the information that we found, yes.

01:16:19

11 Q. So filter complications, again, we're talking about the
12 EVEREST trial. The greatest number of complications is
13 associated with penetrations, followed by tilts and caudal
14 migrations. Do you see that?

15 A. Yes.

01:16:33

16 Q. There's a strong relationship between caudal migrations
17 and tilts. Do you see that?

18 A. Yes.

19 Q. And then there was no relationship was found between IVC
20 diameter and migrations, tilts, and perforations; correct?

01:16:43

21 A. Correct.

22 Q. This is an official report from the company about its
23 review of the EVEREST data; right?

24 A. No. This is not an official report. This is a PowerPoint
25 put together by one of our engineers which we were going to

01:17:00

United States District Court

MICHAEL RANDALL - Direct

1 review.

01:17:04

2 Q. And was he working at Bard at the time he did this?

3 A. Yes.

4 Q. Was he in charge of evaluating the design of the G2 filter
5 at the time he did this?

01:17:10

6 A. He was in charge of gathering this information.

7 Q. Was he in charge of looking at some of the complications
8 that were being caused by the G2 filter?

9 A. He was tasked with doing that.

10 Q. And he was charged with looking at all of the data that is
11 represented in this PowerPoint presentation; correct?

01:17:23

12 A. Correct.

13 Q. Sounds pretty official to me.

14 THE COURT: Is that a question?

15 BY MR. LOPEZ:

01:17:34

16 Q. Is that -- would you agree that this is an official
17 document based on how I just described it?

18 A. Official -- it was generated by a Bard employee, Bard
19 engineer. But when I think of report, I think of something
20 that goes through and has multiple sign-offs so I think it's
21 just the definition.

01:17:48

22 Q. Okay. Well, I don't want --

23 A. But it was generated by an engineer.

24 Q. It was sent by Mr. Andre Chanduszko to you; correct?

25 A. Correct.

01:18:03

United States District Court

MICHAEL RANDALL - Direct

1 Q. To you, a senior engineer at Bard?

01:18:03

2 A. Yes.

3 Q. Okay. Slide number nine, please.

4 This is another one of those Venn diagrams and this
5 is from the MAUDE database; right?

01:18:14

6 A. Yes.

7 Q. And the MAUDE database is where companies and doctors can
8 report adverse events that gets put in a database that is
9 controlled by FDA or I should say made available by FDA?

10 A. Correct.

01:18:35

11 Q. Okay. Now, if you look at the MAUDE, what's being
12 reported in MAUDE, again, this is somebody in the company that
13 is looking at the adverse events that have been reported on the
14 G2 filter?

15 A. Yes.

01:18:49

16 Q. As of -- in fact, this even tells us that it's data as of
17 January 7, 2008?

18 A. Yes.

19 Q. Now we're not going to go through every one of these but
20 you can see that this one talks about penetration, tilt, and
21 caudal migration; right?

01:18:59

22 A. Correct.

23 Q. I think that's what the EVEREST -- just like what we just
24 saw in EVEREST; right?

25 A. Correct.

01:19:17

United States District Court

MICHAEL RANDALL - Direct

1 Q. And just by way of an example, we have 31 cases of caudal
2 migration that included tilt; right? I want to make sure I'm
3 looking at these Venn diagrams correctly. 31 cases of patients
4 where it was reported to MAUDE, 31 caudal migrations and 31
5 tilts?

01:19:21

6 A. 31 caudal migrations in tilt only.

01:19:48

7 Q. In the same patient?

8 A. Correct.

9 Q. And six patients where there was penetration, tilt, and
10 caudal migration; correct?

01:19:59

11 A. Correct.

12 Q. And then 13 patients that had tilt associated with
13 penetration. Same patient?

14 A. Yep, 13 with penetration and tilt.

15 Q. Okay. Let's go to the next page, please. This one
16 includes fractures which we haven't seen before. This is from
17 the MAUDE database. In this we have six patients where it's
18 been reported as of January 7, 2008, in the MAUDE database with
19 caudal migration, tilt, and fractures; correct?

01:20:13

20 A. Right. Correct.

01:20:41

21 Q. And three that involve fractures and tilt?

22 A. Correct.

23 Q. Basically, what we've seen thus far, we've seen a number
24 of patients have been reported in, both the EVEREST trial and
25 from doctors voluntarily out in the field, a number of patients

01:21:02

United States District Court

MICHAEL RANDALL - Direct

1 with a constellation of complications after having received G2
2 filter; correct?

01:21:06

3 A. Yeah. There's reports of complications in patients that
4 have multiple complications within it.

5 Q. In fact, we can see that on the next slide. What does
6 complications mutually exclusive mean? Let me ask you, what
7 does that mean?

01:21:22

8 A. I actually don't remember what that means. I'm trying to
9 figure that out myself.

10 Q. Now, let me ask you, of all the documents that you thought
11 I was going to ask you about today, you knew this was probably
12 going to be the number one document; true? Before you got
13 here?

01:21:51

14 A. No, not necessarily. I looked at all of them.

15 Q. In your deposition which was about six or seven hours --
16 do you remember that?

01:22:04

17 A. Yes.

18 Q. -- about three hours were spent on this document. Does
19 that sound right?

20 A. I don't remember. That was a long day. There was a lot
21 of stuff.

01:22:14

22 Q. It was a long day, a long time was spent on this document
23 that we're seeing here, Trial Exhibit 1222. Do you remember
24 that?

25 A. I remember spending time on this during the deposition,

01:22:31

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MICHAEL RANDALL - Direct

1 yes. How much time, I don't remember.

01:22:33

2 Q. How much time did you spend before you got here today
3 reviewing it so that you could answer questions about
4 everything and anything that was on it?

5 A. This particular one, maybe 20 minutes or so, just kind of
6 went through it.

01:22:46

7 MR. LOPEZ: Could we go to the next slide, please,
8 Greg.

9 BY MR. LOPEZ:

10 Q. Filter complications. Again, this is MAUDE: The greatest
11 number of complications is associated with tilts and
12 migrations, followed penetrations. This is contrary to the
13 EVEREST data.

01:23:01

14 Do you see that?

15 A. Yes.

01:23:27

16 Q. Sir?

17 A. Yes.

18 Q. And then the next sentence: One possible explanation is
19 that some asymptomatic penetrations are not reported.

20 Did I read that correctly?

01:23:40

21 A. Yes.

22 Q. And that means that there may be an unknown number of
23 people who have a G2 filter where the filter has penetrated
24 through the vena cava wall and the company has no idea and the
25 patients have no idea who they are; true?

01:23:56

United States District Court

MICHAEL RANDALL - Direct

1 A. Yeah. This is saying that there could be asymptomatic
2 penetrations.

01:24:00

3 Q. Has Bard, at least by this time, ever organized and
4 conducted a survey asking any doctor who may have prescribed a
5 lot of G2 filters to have their patients come back in to have a
6 radiograph or some kind of an x-ray, 50 patients, to see how
7 many of those asymptomatic patients may have had penetrations
8 they didn't know because about because they don't feel
9 anything? Did the company ever do that?

01:24:16

10 A. I was not in charge of communicating to physicians. I
11 don't know what the company did in regards.

01:24:36

12 Q. And then the next bullet point: MAUDE shows more
13 fractures than EVEREST. One possible explanation is that some
14 tilts and caudal migrations are not reported.

15 The company knew that; right?

01:24:54

16 A. I'm sorry. Can you repeat your question?

17 Q. The company knew what was in bullet point number two?

18 A. That MAUDE shows more fractures than EVEREST.

19 Q. And that a possible explanation is that some tilts and
20 caudal migrations are not reported.

01:25:15

21 A. It says the possible so, yeah, that could be a possible
22 explanation.

23 Q. Well, let me ask you, how many people that had G2 filters
24 as of this date had asymptomatic tilts and a caudal migration
25 and they didn't know about it?

01:25:34

United States District Court

MICHAEL RANDALL - Direct

1 A. I don't know that.

01:25:38

2 Q. How many of these tilts and caudal migrations that were
3 not reported did the company know about?

4 A. I don't know that information or where to get that.

5 Q. Every patient with a G2 filter would have been
6 experiencing this and we just don't know, do we?

01:25:49

7 A. An asymptomatic complication?

8 Q. A tilt and a caudal migration that was asymptomatic?

9 A. I wouldn't say everyone but in terms of the company
10 knowing, that data does not exist.

01:26:12

11 Q. Right. And it doesn't even exist in a small survey that
12 the company could have done of one or two of IVC higher volume
13 interventional radiologists to have maybe 50 of their patients
14 come back in to see what that percentage might be. The company
15 never did that; right?

01:26:31

16 A. Not to my knowledge.

17 Q. Would it be appropriate for your company to represent that
18 just because it wasn't reported, penetrations, tilts,
19 migrations, that it does not exist?

20 A. I'm sorry. Could you repeat that?

01:26:51

21 Q. Yes. In other words, the mere fact that it's not reported
22 does not mean it does not exist in a patient with a G2 filter
23 who is asymptomatic; correct?

24 A. Correct. I think that the asymptomatic part is even that
25 it's not causing symptoms.

01:27:12

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1 Q. We know that. That -- isn't that one of the problems, is
2 that these patients may have all of these conditions and they
3 have no idea because they don't feel anything that would
4 suggest they go to a doctor to find out?

01:27:14

5 A. Yeah, so if it's tilted and you don't know it's tilted,
6 it's not causing harm per se so it's like -- a tilt just means
7 the filter is 15 degrees off of its neutral axis.

01:27:30

8 Q. How about if the company included in their instructions
9 for use or they just had salespeople go out with, you know,
10 just something to leave off at the doctor's office and said, "I
11 want you to monitor your G2 patient for the next two years and
12 I want you to look for silent perforations, migrations,
13 fractures," if the company had done that, don't you think the
14 company would have more information about the true number of
15 these people or the true percentage of these people that
16 actually have that condition with that implant?

01:28:00

01:28:26

17 A. I'm aware that they put in the IFU the results of the
18 clinical study.

19 MR. LOPEZ: Move to strike, Your Honor. It's
20 nonresponsive.

01:28:41

21 THE COURT: Sustained.

22 Please respond to the question.

23 THE WITNESS: Can you repeat the question one more
24 time? I'm sorry.

25 \\

MICHAEL RANDALL - Direct

1 BY MR. LOPEZ:

01:28:46

2 Q. I just want to know if the company had advised doctors
3 that because of some complications with the design of their
4 filter, that if you're going to put one of these in, you want
5 to monitor these patients periodically, six months, every year,
6 and do that, you know, for a two- or three-year period and
7 report back to us what you find, would the company be in a
8 better position to say how many of these filters are out there
9 where this is actually occurring in a patient and the patient
10 doesn't know?

01:28:57

01:29:16

11 A. I suppose they could do that but I don't know how valuable
12 that information would be necessarily.

13 Q. Let me suggest to you -- how about this value? The
14 company says to doctors that they are selling the G2 to and
15 they tell the doctor, "In a year, I want you to take -- after a
16 year you put it in, and I want to you look for tilts,
17 fractures, migrations, and penetrations." Do you follow me so
18 far? Are you, sir?

01:29:41

19 A. Yes.

20 Q. And let's assume when that patient comes in a year later,
21 this device is tilted, it's perforated and it's migrated but it
22 hasn't fractured yet. Are you following me?

01:29:56

23 A. Okay.

24 Q. What if under those circumstances, because the doctor was
25 monitoring the patient, that device was able to be

01:30:14

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1 percutaneously retrieved. Do you follow me so far? Wouldn't
2 that have potentially saved that patient from further
3 migration, further penetration, further -- and the potential
4 risk of a fracture?

5 A. Yeah. I'm not sure if I follow all of that entirely.
6 They do a clinical study and that's how that information is
7 communicated to the physician, because it's a prospective
8 study. Patients are brought in. They are imaged. That's the
9 way to kind of analyze the data.

10 Q. How about the people that are out there that aren't in a
11 study?

12 A. So you're saying have an ongoing study?

13 Q. No. I've said -- you know what I asked you. I asked you
14 whether or not if the company had recommended periodic
15 monitoring so that if the device was starting to tilt, so if
16 the device was starting to penetrate, so if the device was
17 starting to migrate, that it would give the patient and the
18 doctor an opportunity to have it removed before it did more
19 harm, isn't that something that would be -- would have been a
20 good thing for the company to have recommended with respect to
21 the G2 filter?

22 A. I don't know if it would have been a good thing. I don't
23 know how effective that -- what you're saying would have been.
24 Usually tilt and migration, those usually happen -- if they
25 happen, they happen early on and then usually it's done and the

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MICHAEL RANDALL - Direct

1 filter is in that position forever.

01:32:01

2 MR. LOPEZ: Move to strike the nonresponsive portion.

3 THE COURT: Overruled.

4 BY MR. LOPEZ:

5 Q. Well, the reason you don't know what good it would have
6 done is because Bard never did that; right?

01:32:07

7 A. I'm not aware of that for the G2, no.

8 MR. LOPEZ: Let's look at the next slide, please.
9 This is slide number 13.

10 BY MR. LOPEZ:

01:32:32

11 Q. And this reads: Caudal migration, tilt, perforation and
12 fractures are the most commonly occurring complications
13 associated with the filter.

14 Did I read that correctly, sir?

15 A. Yes.

01:32:42

16 Q. Eliminating these failure modes would reduce the number of
17 filter complaints by 78 percent.

18 Do you see that?

19 A. I see that.

20 Q. And that hadn't been done yet; right?

01:32:55

21 A. No.

22 Q. Those failure modes had not been reduced as of mid-2008;
23 correct?

24 A. For the G2, no.

25 Q. So let's look at the next slide, number 14. I'm not going

01:33:20

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MICHAEL RANDALL - Direct

1 to run through this. I'll probably get dizzy. But do you see
2 where it says design? Design?

3 A. Yes.

4 Q. So, obviously, the company was looking at design as being
5 a cause of everything we've talked about thus far; correct?

6 A. Let me just get my bearings here with what this is. Okay.

7 Q. And then, again, I don't want to walk you all the way
8 through it but one of the design problems could have been
9 insufficient caudal anchoring. Do you see that?

10 A. Yes, I do.

11 Q. Did anyone at the company tell you that they knew that
12 that was a problem with the design about three or four months
13 after they put it on the market, that it required caudal
14 anchoring?

15 A. No.

16 Q. And as of the date that we're talking about here in
17 mid-2008, there had been no caudal anchoring added to the G2
18 filter to prevent caudal migration; true?

19 A. Yeah, there was no caudal anchors added.

20 Q. As a matter of fact, before we go through the rest of this
21 slide, none of that was done even in response to this project;
22 true?

23 A. None of what was done in response?

24 Q. In other words, these fixes, the caudal anchors, this G2
25 Platinum plan was abandoned wasn't it?

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MICHAEL RANDALL - Direct

1 A. Yeah. We actually failed on this project. We tried to
2 make it work and we couldn't. So we scrapped this and then
3 there was another design that we went with.

01:34:50

4 Q. You couldn't figure out how to turn the hooks upside down?

5 A. It's not as simple as that.

01:35:03

6 Q. Well, you know Greenfield did that.

7 A. The Greenfield is a titanium device that is single level.

8 Our device is a bilevel filter so -- and it's a conical shape.

9 So when you put it in different diameters, the contact angle to

10 the wall changes. So putting a caudal anchor on the filter,

01:35:22

11 it's extremely tough to do.

12 Q. Okay. Now, let me see if I understand what you're saying.

13 You're saying that you actually took steps to design a filter

14 that had all of these fixes on it for caudal migration,

15 penetration, and fracture? You did all of that?

01:35:40

16 A. There was projects under way to improve those things you

17 talked about.

18 Q. Projects is different than whether or not you took steps.

19 My question is very precise.

20 A. Okay.

01:35:55

21 Q. You said that you couldn't do it. That means you tried to

22 do it. Did you try to do it in 2008 and 2009?

23 A. Yes.

24 Q. You actually have mock-up models where you tried to put a

25 caudal anchor and tried to prevent this thing from penetrating

01:36:08

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MICHAEL RANDALL - Direct

1 into the vena cava?

01:36:12

2 A. In the G3 project, that is what that was supposed to be.
3 Remember I told you there was parallel paths. There were many
4 projects going on so the G3, there was a ton of filters that
5 were created, put into animals, assessed, and this is one that
6 would have required a clinical study.

01:36:28

7 But the devices caused something else to happen so
8 instead of now the device is not moving caudally, what we saw
9 in animals was that it was penetrating. So it's one of these
10 things you try and fix something but it can make something
11 worse so you have to be careful when you're designing.

01:36:50

12 Q. Okay. Let me see if I can understand what you're saying.
13 So you knew all of these things had to happen to the G2 filter
14 to create all of these problems because that's what was
15 discussed at this meeting?

01:37:07

16 A. We knew that there were some improvements that we could do
17 to our product, yes.

18 Q. Right. And you tried and you failed for a number of years
19 before you were able to do that; correct?

20 A. The G2 Platinum project failed. But then we came back
21 with a project called Eclipse and that one we were successful.
22 And then Meridian, we were successful. We were running that in
23 parallel as well. And then we had another one called G3, that
24 one failed. And then we also had another one called Denali
25 which ultimately is what we sell now.

01:37:19

01:37:40

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1 Q. Well, everything you just said, how is that going to help
2 any patient who had a G2, the fact that you were trying and
3 failing and trying and failing and you were fixing one thing
4 and then fixing another thing, how that going to help anybody
5 with a G2 filter who was experiencing caudal migration, tilt,
6 fracture, and perforation?

01:37:43

01:37:56

7 A. So I think -- so you keep using the word -- like issue.
8 All filters, all filters on the market have complications.

9 MR. LOPEZ: Move to strike Your Honor. That's not
10 responsive.

01:38:12

11 THE COURT: Overruled.

12 THE WITNESS: They are very low rates so it's not
13 like this device is bad. It was a good filter.

14 So it's while that filter was in the market, we
15 looked and said, "Hey, how can we make it better? We want to
16 be the leaders." So we had multiple projects on what can we
17 deliver first to the customer and what were some long-term
18 things that we could deliver and that is essentially one of
19 the -- I think the best things about Bard. We were constantly
20 innovating. We had a lot of engineers working in filters.

01:38:25

01:38:42

21 BY MR. LOPEZ:

22 Q. Sir, my question was: How does the fact that this company
23 could not figure out how to fix the G2 filter help people that
24 had a G2 filter from increased risk of caudal migration,
25 perforation, fracture, and penetration?

01:39:02

United States District Court

MICHAEL RANDALL - Direct

1 MR. CONDO: Objection, Your Honor. It's
2 argumentative.

01:39:05

3 THE COURT: Overruled.

4 THE WITNESS: So those complications still exist.
5 They are in a low amount so we're making improvements and we
6 were able to make improvements in the future and future
7 generations.

01:39:13

8 MR. LOPEZ: I'm going to move to strike as
9 nonresponsive, Your Honor.

10 THE COURT: Sustained.

01:39:29

11 Please respond to the question.

12 THE WITNESS: Can you say it one more time?

13 BY MR. LOPEZ:

14 Q. The truth that -- all of these failures, to fix all of
15 these problems, in the meantime we've got patients with G2
16 filters in them and they still are exposed to all of these
17 complications and design defects in the G2 filter; true?

01:39:38

18 A. There are still complications in filters?

19 MR. LOPEZ: Okay. Let's go to the next slide,
20 please.

01:40:00

21 BY MR. LOPEZ:

22 Q. Do you know if Bard put out an APB or safety alert to
23 people with the G2 filters and said, "By the way, we know we've
24 got to fix caudal migration. We know we've got to fix tilt.
25 We know we've got to fix penetrations and perforations and

01:40:13

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MICHAEL RANDALL - Direct

1 fractures but we're still trying to figure it out." Did they
2 put out an alert like that?

3 A. I'm not aware of it.

4 Q. Don't you think that might have been a good idea for
5 people who you were just gathering data from to help design
6 your next device that they should have known that that was
7 going on?

8 A. Are you asking me do I think it would have been a good
9 idea to put out an alert?

10 Q. Yeah.

11 A. No. I think we had enough data. We knew how we could
12 improve the design.

13 Q. Well, the data you were getting from the complications
14 that were being experienced in people like Ms. Booker, that's
15 where you were getting the data; right?

16 A. The MAUDE database as well as the EVEREST.

17 Q. Right. And did they know that they were providing you
18 data for you to help design the next model of your G2 filter --
19 I mean, of your IVC filters? Did they know that? Did the
20 patients who had the G2 filter know that they were providing
21 data for purposes of fixing the device that they had in them?

22 A. Yeah, I don't think patients know that they are providing
23 data because the hospital usually reports the data and
24 physicians.

25 Q. Okay. Let's look at slide 15.

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MICHAEL RANDALL - Direct

1 G2 filter operates in a dynamic environment over a 01:41:40
2 wide IVC diameter.

3 Do you see that, sir?

4 A. Yes.

5 Q. And let's go down to the last sentence of that full 01:41:46
6 paragraph where it begins: The following are potential causes
7 of the complications.

8 Do you see where I am?

9 A. Yes.

10 Q. Filter design, caudal migration, filter instability, 01:41:57
11 mainly insufficient caudal anchoring.

12 Did I read that correctly?

13 A. Correct.

14 Q. There was a design defect that you recognized that needed
15 to be fixed to prevent caudal migration? 01:42:10

16 A. I wouldn't use those words.

17 Q. Well, if it requires a redesign to fix the dangerous
18 performance or safety profile of your device, you don't think
19 that's a redesign or a fix?

20 A. I wouldn't use those words. 01:42:28

21 Q. You wouldn't use the word "fix"?

22 A. I wouldn't use fix or the other words you said.

23 Q. Do you know if patients who had these devices knew that
24 the device was not designed to prevent caudal migration?

25 A. The design had -- it's a filter so it has radial strength. 01:42:57

MICHAEL RANDALL - Direct

1 Q. I just want to know if your patients knew this, sir.

01:43:01

2 That's all I'm asking you, sir. Did patients know that? Did
3 the patients know what you knew about what was going on with
4 the G2 factor and the fact that it needed all of these design
5 fixes?

01:43:13

6 A. The patients did not know about the enhancements we were
7 working on.

8 Q. Did they know that about tilt, filter instability, mainly
9 insufficient IVC wall apposition and/or caudal anchoring, did
10 they know that was going on with the G2 device that was in
11 their bodies?

01:43:28

12 A. I do not believe that information was given to the
13 patients. Information for complications were listed in the
14 IFU.

15 Q. Were doctors told that we need caudal anchoring for our G2
16 filter and we need better apposition and/or caudal anchoring to
17 prevent tilt in the G2 filter?

01:43:44

18 A. You asked did doctors say that?

19 Q. Did you tell doctors that?

20 A. Did we tell doctors that they --

01:44:00

21 Q. That your device had needed caudal anchoring because it
22 was insufficient to deal with caudal migration?

23 A. What this is saying is that there is --

24 Q. Sir, I just want to know whether doctors knew what I just
25 asked you. That's all I'm asking.

01:44:23

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MICHAEL RANDALL - Direct

1 A. I think in the IFU, migration, caudal migration is listed
2 as a complication and the rates from EVEREST. That's what was
3 communicated.

4 MR. LOPEZ: Move to strike as nonresponsive, Your
5 Honor.

6 THE COURT: Overruled.

7 BY MR. LOPEZ:

8 Q. Sir, did you tell doctors that your company was selling G2
9 filters to that we have insufficient caudal anchoring on the G2
10 which was causing caudal migration? Can you answer that yes or
11 no?

12 A. I'm not in charge of communicating with physicians. I'm
13 an engineer so I can answer what's in my world, but you're
14 saying what's being communicated to physicians. I don't know.

15 Q. Now, what is insufficient IVC wall apposition?

16 A. In the context of tilt, this means the amount of the vena
17 cava filter in contact with the IVC wall. The more filter in
18 contact with the wall, then probably the more stable.

19 Q. And because this is under filter design, that was a design
20 issue and problem in the G2 filter; correct? What you just
21 described.

22 A. So this is basically a hypothesis. It says "potential
23 causes." It's not saying that it had insufficient. It's
24 saying there's an opportunity here to potentially put more wall
25 apposition of the filter and that might help improve

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1 resistance.

01:46:18

2 Q. You've had almost three years to investigate whether or
3 not that might be a problem with the filter. Don't you think
4 that you may have come up with at least a reasonable reason why
5 that was happening three years later?

01:46:28

6 A. Three years later about the tilt?

7 Q. Let me strike the question.

8 A. I don't understand the question.

9 Q. I'm sorry. If you can just cooperate and answer my
10 question, we'll get through this a lot faster.

01:46:44

11 A. I'm trying to.

12 THE COURT: Excuse me. Counsel, hold on.

13 Mr. Lopez, if you want him to answer a question yes
14 or no, please tell him when you ask the question.

15 MR. LOPEZ: Okay. I'll do that.

01:46:56

16 THE COURT: And Mr. Randall, if you can't answer it
17 yes or no you can tell him you can't answer it yes or no.

18 THE WITNESS: Thank you.

19 BY MR. LOPEZ:

20 Q. Insufficient wall apposition was a possible cause of a
21 complication of tilt that your company was discussing in June
22 of 2008; right?

01:47:03

23 A. Yes.

24 Q. And perforation -- what is radial pressure?

25 A. Radial pressure, if you look at the filter, it's the

01:47:21

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1 amount of force that is exerted by the filter on the ID 01:47:23
2 (phonetic) of the vena cava, so it basically holds it in place.

3 Q. So this company in 2008 thought that radial's pressure
4 might be what was causing perforations; right?

5 A. No. It's a possibility. 01:47:45

6 Q. Right. You were thinking that at the time?

7 A. It was a potential.

8 Q. And then perforation, another possibility that you were
9 thinking about was filter instability that was resulting in
10 tilt; right? Was causing perforations? In other words, the 01:48:00
11 fact that this device was unstable and was tilting actually
12 could be causing perforation?

13 A. That was a potential cause.

14 Q. And you saw that in the EVEREST study where there was
15 tilting related to perforation. You saw that in the EVEREST 01:48:17
16 study, right, results?

17 A. We saw results where a tilt and a perforation existed in
18 the same filter.

19 Q. Okay. Let's look at the next slide, please.

20 Now this is more than a hypothesis. It's a belief, 01:48:36
21 right, when you say it is believed that caudal migration leads
22 to tilts, perforations, and fractures; correct?

23 A. I don't know if that was the final --

24 Q. Sir, is that what it says.

25 A. But in this Lidek, it says that. 01:48:51

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MICHAEL RANDALL - Direct

1 Q. In other words, if you fix caudal migration by anchoring
2 it with caudal hooks, it might just fix the tilt, perforation,
3 and fracture problem with the G2. You were thinking about that
4 at the time; right?

01:48:56

5 A. We were thinking caudal migration, if you improve caudal
6 migration, it can improve a lot of complications.

01:49:09

7 Q. And that didn't happen with the G2 filter before it got
8 taken off the market, none of that. No caudal anchors, that
9 you can to fix perforations, migrations, fractures before the
10 G2 was taken off the market; right?

01:49:31

11 A. Well, you said nothing happened to the G2 filter. The
12 improvements we made were to the G2 filter.

13 Q. I want to talk about the G2 filter that remained on the
14 market. No new designs until what, about 2011?

15 A. It's when Eclipse came out. I think it was -- you're
16 talking caudal specifically? Because there was an
17 electropolishing project. That was I think 2009, 2010.

01:49:53

18 Q. Sir, I'm talking about the G2 filter that was -- that has
19 been on the market since January of 2005. That stayed on the
20 market unaltered except for the hook put on the top until about
21 2011; is that correct?

01:50:12

22 A. Yeah. Eclipse is also essentially a G2 filter with a hook
23 and then electropolishing. And Meridian is the G2 filter with
24 the hook, electropolishing and caudal anchor so that's how the
25 filter evolved.

01:50:39

MICHAEL RANDALL - Direct

1 Q. But Ms. Booker never got those devices. They got the G2.
2 She got the G2.

3 A. I don't think those were available at that time.

4 Q. Okay. Let's look at the solutions slide which is the next
5 one.

6 G2 Platinum will be developed with the following
7 improvements relative to the current G2 platform in order to
8 reduce complaints: Reduced fractures, electropolished filter
9 surface, low inclusion, wire.

10 Correct?

11 A. Correct.

12 Q. And electropolishing was not a new phenomenon to assist
13 metals in reducing their fracture rates; true? Can you answer
14 that yes or no, sir? Electropolishing was not a new phenomenon
15 that would assist a metal like Nitinol to become more
16 fracture-resistant?

17 A. No.

18 Q. That's true; right?

19 A. For Nitinol? It helps Nitinol.

20 Q. Yes. Be more fracture-resistant?

21 A. I believe does it.

22 Q. And Ms. Booker did not get an electropolished IVC filter;
23 true?

24 A. G2 was not electropolished.

25 Q. And then the next one: Reduced tilt, penetration,

United States District Court

MICHAEL RANDALL - Direct

1 migration, design changes. That was the solution?

01:51:55

2 A. For this particular project, we believed we would address
3 those potential complications with a design change.

4 Q. Okay. And the design changes were on the G2; right?

5 A. The improvements we were going to make.

01:52:16

6 Q. Because the current design of the G2 is what resulted in
7 increased tilt, increased penetration and increased migration.
8 Is that true, sir? Can you answer that yes or no?

9 A. No, I cannot. I don't understand the question. You said
10 increased, the G2 increased that relative to what --

01:52:35

11 Q. I said increased because if you reduce something, that
12 means it must have been higher at one time. So the idea
13 that -- the reason why G2 had the level of tilt, penetration,
14 migration, and fractures was because of design issues that
15 needed to be changed; true?

01:52:55

16 A. I can't respond to true or false on this but I can answer
17 that further if you like.

18 Q. No. That's okay. I just need you to answer that
19 question. You can't answer that whether or not that's true?

20 A. No.

01:53:12

21 Q. Okay. Let's go to the next page for solutions.

22 The following tests will be performed to test new
23 filter designs.

24 So you're looking at redesigning the G2; correct?

25 This is not about Eclipse. This is about the G2.

01:53:25

United States District Court

MICHAEL RANDALL - Direct

1 A. Yeah, we were making improvements to our current filter on 01:53:38
2 the market which was G2 at the time.

3 Q. Did you tell doctors that?

4 A. That we're constantly making improvements?

5 Q. Did you tell doctors that the G2s in patients that they 01:53:48
6 had put them in required some design changes that take care of
7 caudal migration, tilt resistance, radial strength,
8 perforation, and fatigue. Did you tell doctors?

9 A. That it requires design change to improve that? No. We
10 don't necessarily tell people how we improve every product 01:54:11
11 line.

12 Q. I'm just talking about the G2. Did doctors know that
13 there was some design issues with the G2 that needed to be
14 fixed because of what you saw in MAUDE and what you saw in the
15 EVEREST study regarding migration, tilt, perforation, and 01:54:25
16 fractures? Can you answer that yes or no?

17 A. No.

18 Q. No, that you did not tell doctors; right?

19 A. No, I cannot answer your question with a yes or no.

20 Q. So you can't tell me, as you sit there today, whether or 01:54:39
21 not the company advised doctors of something?

22 A. That if the company advised doctors of?

23 Q. That there were some design issues with the G2 that needed
24 to be fixed.

25 A. Can I say that the company told -- I'm sorry. 01:54:56

United States District Court

MICHAEL RANDALL - Direct

1 Q. My question is simple. Did the company tell doctors,
2 "We've got a design problem with the G2 that is causing
3 migrations, fractures, perforations, and tilts that we need to
4 fix"?

01:55:00

5 A. To my knowledge, I don't think so but I'm not in charge of
6 communicating with the physician. I'm an engineer so I don't
7 talk or deal with the physician like that.

01:55:14

8 Q. So what happened with the G2 is the company continued to
9 gather information about caudal migration, tilts, fractures,
10 and perforation to help them design their next device? Is that
11 what happened? They just continued to gather information from
12 patients who were being hurt --

01:55:35

13 A. No.

14 Q. -- where the device was failing to help them design the
15 next device?

01:55:56

16 A. No. I do not agree with that statement.

17 Q. Okay. Now, did Bard have an option to take the G2 and the
18 G2X off the market until it could get a safer filter on the
19 market? Did they have that option?

20 A. Can we take a device off the market? Is that what you're
21 asking? Because it's almost --

01:56:28

22 Q. They had option?

23 A. Yes. Any company can remove any device that they put on
24 the market.

25 Q. And, sir, at your deposition that was taken on February 2,

01:56:38

United States District Court

MICHAEL RANDALL - Direct

1 2017, let me ask you if you still agree with this. Page 263,
2 line 19: In order to know if a filter is safer versus another
3 you need to have a clinical study in which both filters are
4 placed and they have appropriately powered and a comparison is
5 made with them. But there was no study done; correct?

01:56:44

01:57:34

6 You testified to that in February of 2017?

7 A. That there was no studies done between the G2 versus
8 Denali.

9 Q. Or comparing any two devices. The company never did that?

10 A. No.

01:57:53

11 Q. Is that true that the company did not do that?

12 A. Run two filters in the same clinical study? No, they did
13 not do that.

14 Q. And, sir, one of the reasons you didn't want to do a
15 clinical trial, which we saw in one of the earlier slides, is
16 because that was going to delay getting the next iteration of
17 the Bard filter on the market; true?

01:58:17

18 A. For that particular project, like I said, there were
19 multiple filter projects ongoing. One was going to require a
20 clinical study. The other one was meant to deliver
21 improvements quickly or faster. So that's what we did.

01:58:44

22 Q. Sir, would you just answer my question? My question is
23 simple. That one of the reasons you didn't want to do a
24 clinical trial on the G2 was because it was going to delay
25 getting the next iteration of the Bard filter on the market?

01:59:00

United States District Court

MICHAEL RANDALL - Direct

1 A. No. That is not correct.

01:59:06

2 Q. Okay. Can you look at page 189 of your deposition. Line
3 12. Do you see where I am and you were asked this question:

4 And assuming that this is in or around June of 2008
5 or after, the only way you're going to have a 2009 launch date
6 is without a clinical trial; right?

01:59:32

7 And you answered: Yes, that makes sense.

8 And then were you asked: If you have a clinical
9 trial, it's going to delay that substantially; right?

10 Answer: It would -- I believe it would take longer
11 than Q4 2009 if a clinical were involved.

01:59:50

12 Did I read that correctly?

13 A. Yes. That's what it says here. I'm not sure in context
14 what project we're talking about, though.

15 Q. And all of the things we just talked about on that last
16 exhibit, this G2 Platinum, that project was abandoned; correct?

02:00:08

17 A. Yeah. We failed that project.

18 Q. You abandoned?

19 A. I wouldn't say abandoned. We couldn't make it work. We
20 found another project work.

02:00:28

21 Q. I'm not understanding that. Did you actually take steps
22 as part of the G2 Platinum to test a device that would have
23 fixed all of those things?

24 A. Yeah. Do you want me to tell you what progressed with
25 that project?

02:00:43

United States District Court

MICHAEL RANDALL - Direct

1 Q. No. The G2 -- let me ask you this. When did you abandon
2 the G2 Platinum project?

3 A. I don't know if it was in 2008. I think it was
4 relatively -- we knew relatively in a quick amount of time that
5 when we electropolished the entire filter, that's what we were 02:00:44
6 trying to do. That's why we called it platinum. We were going
7 to electropolish the entire filter and it removes basically
8 thin layers of the Nitinol surface, makes it more polished and
9 it was eating away the weld to hold the device together. So we
10 couldn't go with that solution. And then that's when we went 02:01:00
11 and we did the project called Veil which became Eclipse and
12 instead of electropolishing the whole filter, we
13 electropolished every single component, which was even more
14 challenging, and then we got that project out. And then in
15 parallel we did Meridian because we couldn't get it on the 02:01:21
16 Eclipse design where we added the caudal anchor. There was a
17 lot of filter activity going on. 02:01:39

18 Q. But I'm talking about the G2 filter right now. The G2
19 filter that you were talking about in that last exhibit that
20 described all of those design changes, described all of those 02:01:56
21 complications, the G2 --

22 A. M'hum.

23 Q. -- remained unfixed and remained the same design from 2005
24 until it got taken off the market in 2011; correct?

25 A. I wouldn't use those words. I cannot say -- I can't give 02:02:11

MICHAEL RANDALL - Direct

1 you a yes-or-no answer.

02:02:15

2 Q. Did it stay on the market as designed in 2005 until 2011?

3 A. Yes.

4 Q. Did any of the patients that had a G2 filter, were any of
5 them told any of the information that was contained in that
6 PowerPoint slide we just went through, that that device
7 required all of those design changes to fix some issues, some
8 safety issues, with the device?

02:02:29

9 A. I wouldn't use that terminology or the way you are wording
10 it, no.

02:02:47

11 Q. How would you phrase it? I'm asking you a simple
12 question. Were any of the patients who had a G2 filter told of
13 anything about the information that you had in that PowerPoint
14 slide we just went through?

15 A. We did not communicate our PowerPoint slide to any
16 patients.

02:03:01

17 Q. Were any of the doctors that were prescribing G2 filters
18 or who had patients with G2 filters advised of any of the
19 information that was contained in that PowerPoint slide that
20 you and I just struggled going through?

02:03:14

21 A. No. That slide was an internal document.

22 Q. Right. None of that information got out to doctors.

23 A. The hypothesis in that PowerPoint slide did not get out
24 to --

25 Q. Sir, there was more than a hypothesis in there. There

02:03:32

United States District Court

MICHAEL RANDALL - Direct

1 were plans and solutions and data about the complications that
2 were experienced with that device; true?

02:03:35

3 A. There was data on the complications and there were
4 potential solutions that were potential improvements that we
5 were contemplating on doing.

02:03:51

6 Q. Now, I don't know how many slides there were, 61. My
7 voice is hoarse so it must have been a lot. I didn't see the
8 word "hypothesis" in there once. You brought that word to this
9 courthouse, hypothesis.

10 THE COURT: Is that a question?

02:04:08

11 MR. LOPEZ: Yes.

12 BY MR. LOPEZ:

13 Q. Sir, is that true?

14 A. It's actually in a lot of our documents when we talked
15 about this.

02:04:14

16 Q. I'm talking about the PowerPoint slide that you and I just
17 went through. This doesn't talk about hypothesis, does it?

18 A. It uses the word "potential."

19 Q. Yeah. And it also uses the word "solutions"; right?

20 A. If you say so.

02:04:30

21 Q. And it uses a lot of other words in here but not the word
22 "hypothesis"; true?

23 A. I don't recall in that particular PowerPoint but in other
24 PowerPoints, when we discuss it, we use the word "hypothesis."

25 Q. But not today?

02:04:49

United States District Court

1 A. Not in that -- I don't think so in that 2008 slide. 02:04:51

2 Q. All right.

3 MR. LOPEZ: That's all the questions I have for now,
4 Your Honor.

5 THE COURT: Cross-examination? 02:04:57

6 MR. CONDO: No questions, Your Honor.

7 THE COURT: All right. Thank you, sir. You can step
8 down.

9 (Witness excused.)

10 THE COURT: All right. Your next witness, counsel? 02:05:09
11 If you want to stand up, ladies and gentlemen, feel
12 free.

13 All right. Counsel, your next witness, please.

14 MR. LOPEZ: We're going to play a short video, Your
15 Honor. I'm putting on the next witness and I'm going to try to 02:06:26
16 get my voice back a little bit. It's a short video.

17 THE COURT: All right.

18 MS. REED ZAIC: The next videotaped witness will be
19 Daniel Orms. In 1988 Daniel Orms received his bachelor's
20 degree in business with a specialization in marketing. 02:06:59

21 Mr. Orms began selling medical devices for Johnson & Johnson
22 subsidiary Ethicon in 1991. Mr. Orms worked for a number of
23 medical device companies selling their devices before he
24 started working for what is now Bard Peripheral Vascular in
25 1997 as a sales representative. He became a district sales 02:07:18

1 manager in 2001 and then a regional sales manager in 2008. 02:07:22

2 During this time at Bard, Mr. Orms sold Bard's Simon Nitinol
3 Recovery and G2 filters and oversaw the district and regional
4 sales representatives who sold these filters.

5 Mr. Orms was laid off from Bard in December of 2012 02:07:40
6 and is currently employed as a regional manager for Abbott
7 Vascular, another medical device maker.

8 (Whereupon the video deposition of Daniel Orms was
9 played.)

10 MR. LOPEZ: At this time, Your Honor, plaintiffs call 02:14:03
11 Mr. Rob Carr.

12 COURTROOM DEPUTY: Sir, if you would please come
13 forward and stand right here and raise your right hand.

14 (ROBERT M. CARR, JR., a witness herein, was duly
15 sworn or affirmed.) 02:20:28

16 COURTROOM DEPUTY: Could you please state your name
17 and spell your last name?

18 THE WITNESS: Robert Michael Carr, Jr. C-A-R-R.

19 COURTROOM DEPUTY: Thank you, sir. Please come have
20 a seat. 02:20:47

21 **DIRECT EXAMINATION**

22 BY MR. LOPEZ:

23 Q. Good afternoon.

24 A. Good afternoon.

25 Q. Introduce yourself to the jury, please. 02:21:07

ROBERT M. CARR, JR. - Direct

1 A. Hi. My name is Robert Carr.

02:21:09

2 Q. And I'm not sure what we want to do with these but these
3 are copies of all of the depositions and some trial testimony
4 you've given in the past regarding IVC filters.

5 MR. LOPEZ: Can I have this up there?

02:21:25

6 BY MR. LOPEZ:

7 Q. I tried to put them in chronological order to make it a
8 little easier for you in case you need it.

9 Okay. Mr. Carr, you actually started with NMT,
10 right, Nitinol Medical Technologies?

02:21:58

11 A. Yes, I did.

12 Q. And I think you have been designated many times as the
13 person most knowledgeable about Bard IVC filters by the
14 company; true?

15 A. Yes.

02:22:15

16 Q. On a number of issues; correct?

17 A. Yes.

18 Q. And when you were at NMT, you were working on the Recovery
19 filter project; correct?

20 A. Among others, yes.

02:22:27

21 Q. In fact, we saw your name come up with Dr. Asch. You were
22 involved in the Asch study?

23 A. I was.

24 Q. And your name was mentioned in the migration report that
25 happened in the Asch study. Do you recall that?

02:22:39

United States District Court

ROBERT M. CARR, JR. - Direct

1 A. Yes.

02:22:43

2 Q. And you also got a lot of exposure while at NMT to the
3 Simon Nitinol filter; right?

4 A. Yes. I worked very closely with Dr. Simon.

5 Q. During the time that you were at NMT which at least,
6 according to one or more of your depositions, was in 1996 until
7 NMT was sold to Bard?

02:22:58

8 A. The filters were sold to Bard. The whole company was not.
9 But, yes, from '96 to 2002.

10 Q. All right. Thanks for that correction. But NMT sold the
11 technology of their filters to Bard; correct?

02:23:23

12 A. Yes.

13 Q. And that transaction was happening while the Recovery
14 filter was being tested and it was while the Asch study was
15 going on; true?

02:23:43

16 A. I'm not sure if the study was completed by then but around
17 the same time.

18 Q. Now, the original decision to start looking at a
19 retrievable device happened while NMT was still the company
20 that was -- I guess you could say owned the technology; true?

02:24:02

21 A. Yes. In fact, it was Dr. Simon's idea to develop a
22 removable filter.

23 Q. But Bard had an interest in that project as well, didn't
24 they, during that period of time?

25 A. Ultimately, yes.

02:24:21

United States District Court

ROBERT M. CARR, JR. - Direct

1 Q. Well, I mean, actually, when the Asch study was going on,
2 there was a lot of participation by both NMT folks and Bard
3 folks?

02:24:24

4 A. Bard's participation was they brought Dr. Asch to our
5 knowledge. We didn't know Dr. Asch. He was the -- a client of
6 Bard Canada's at the time.

02:24:39

7 Q. Did you do work on the Simon Nitinol filter while you were
8 at NMT?

9 A. I worked on a project to bring the manufacturing of the
10 Simon Nitinol filter to NMT. We had prior to that had
11 contracted another company to actually make the device for us.

02:24:57

12 Q. While you were at NMT -- as a matter of fact, let's just
13 talk about the entire time that you had exposure to the Simon
14 Nitinol filter, whether at NMT or Bard.

15 Was there ever a health hazard evaluation prepared
16 for any adverse events related to the Simon Nitinol filter?

02:25:20

17 A. Not to my knowledge, no.

18 Q. How about Remedial Action Plans?

19 A. No, not to my knowledge.

20 Q. Did you ever have to contact a PR media firm to deal
21 with --

02:25:40

22 A. (Witness coughing). I'm sorry. I have water. The first
23 cup of water was the problem. I have water. I'm good.
24 Thanks.

25 Q. Was there ever a reason to hire a media firm or a PR firm

02:26:04

United States District Court

ROBERT M. CARR, JR. - Direct

1 to deal with the potential of a crisis communication plan 02:26:08
2 because of issues involving the Simon Nitinol filter?

3 A. No.

4 Q. Now, before the actual transaction where NMT's technology
5 was sold to Bard, there was a dispute between the two companies 02:26:34
6 about whether or not NMT could sell to someone else or whether
7 or not they had to sell it to Bard? Do you remember that?

8 A. I do, yes.

9 Q. And do you also remember that that dispute lasted for a
10 year or more before it was resolved? 02:26:50

11 A. I don't know the timing of it.

12 Q. Do you remember that during that period of time that other
13 than the Asch study, that research and development essentially
14 shut down with respect to the Recovery filter?

15 A. I wouldn't characterize it as shut down. The development 02:27:07
16 of the filter was completed and the Asch study was either
17 ongoing or had just finished.

18 Q. And is the main reason that NMT thought that a -- selling
19 the device and the technology to Bard is because Bard had
20 commercial contacts with doctors. They had a sales force and 02:27:29
21 they had relationships with hospitals?

22 A. I'm sorry. I think I misunderstood your question.

23 Q. In other words, while you were at NMT, one of the reasons
24 they thought selling it to Bard was a good idea is because they
25 had a huge sales force and they had relationships with doctors 02:27:48

United States District Court

ROBERT M. CARR, JR. - Direct

1 and hospitals; true?

02:27:52

2 A. Bard was the commercial arm, if will you, the distributor
3 of the Simon Nitinol filter for, at that point, probably at
4 least six or seven years. So they were certainly a reasonable
5 and logical partner.

02:28:09

6 Q. And then once the technology and all this litigation
7 resolved and Bard took over the technology, that was sometime
8 in the latter part of 2001. Does that sound about right?

9 A. I think it was in the October time frame.

10 Q. Okay. And you were an employee of NMT at the time;
11 correct?

02:28:30

12 A. Yes, I was.

13 Q. And then did you eventually get hired by Bard?

14 A. I did, in July of 2002.

15 Q. Okay. And were you hired as an engineer?

02:28:46

16 A. Yes.

17 Q. And were you hired primarily to help with the
18 commercialization of the Recovery filter?

19 A. I was hired and my responsibilities were in vena cava
20 filters and angioplasty balloons and biopsy devices at the
21 time.

02:29:06

22 Q. You led the commercialization of the product when you got
23 to Bard; right?

24 A. I wouldn't term it the commercialization. I led the team
25 that developed and ultimately commercialized the product.

02:29:22

United States District Court

ROBERT M. CARR, JR. - Direct

1 Q. And when you got to Bard, anytime after the technology was 02:29:27
2 sold to Bard, did Bard have an opportunity to look at all of
3 the testing and all of the science and all of the things that
4 existed with respect to the Recovery filter as part of their
5 due diligence? 02:29:47

6 A. Of course.

7 THE COURT: All right. We're going to break at this
8 point. We'll resume at 2:45. We'll excuse the jury.

9 MR. LOPEZ: Okay. Thank you, Your Honor.

10 (Jury departs at 2:30.) 02:29:58

11 (Recess at 2:31; resumed at 2:45.)

12 (Jury enters at 2:45.)

13 (Court was called to order by the courtroom deputy.)

14 THE COURT: Thank you. Please be seated.

15 You may continue, Mr. Lopez. 02:46:14

16 BY MR. LOPEZ:

17 Q. Mr. Carr, with respect to the Asch pilot study, again, you
18 were involved in the investigation regarding the migration. I
19 think it was patient number nine.

20 A. Yes, I was. 02:46:32

21 Q. And do you recall that there was a legitimate concern that
22 patient number nine was not in the study that the Recovery
23 filter actually could have continued migrating to that
24 patient's heart?

25 A. I'm sorry. I don't understand the question. 02:46:49

United States District Court

ROBERT M. CARR, JR. - Direct

1 Q. Well, there was a concern had that patient not been in a
2 study closely monitored and was not in a clinical trial or
3 pilot study that the device could have actually continued to go
4 to his heart and cause his death.

02:46:53

5 A. I wouldn't put it that way, no. It was observed through a
6 film study for a different reason and that's how it was
7 observed. The filter never moved or went to his heart.

02:47:10

8 Q. Okay. Let's look at your deposition. It's November 5 of
9 2013.

10 MR. LOPEZ: Is that one of the ones that you can put
11 up electronically? Why don't we just do that and we'll make it
12 easier for you.

02:47:33

13 Q. Your deposition on November 5, 2013, starting at page 119,
14 line 17?

15 THE COURT: Do you want him to look at it or are you
16 going to put it up electronically?

02:47:57

17 MR. LOPEZ: It's easier if we put it in
18 electronically, Your Honor. He's got it now. It's in front of
19 him.

20 BY MR. LOPEZ:

02:48:07

21 Q. Now, you were asked at your deposition -- do you remember
22 having many depositions taken in this case, sir?

23 A. I have been deposed several times, yes.

24 Q. And you know that testifying in a deposition is like
25 testifying in court. You're sworn to tell the truth; right?

02:48:19

United States District Court

ROBERT M. CARR, JR. - Direct

1 A. Of course.

02:48:23

2 Q. You were asked on line 17: Now, going back to this major
3 migration event, nobody knows what would have happened to this
4 patient had it not been discovered?

5 You answered: Nobody knows what would have happened.

02:48:37

6 And then Mr. Johnson asks again on page 120, line
7 three: But there is a concern or was a concern on your part,
8 Dr. Kaufman's part, on everybody's part, that if it had not
9 been discovered and if the filter had not been removed, this
10 filter may very well have migrated further and caused serious
11 injury and/or death to this patient?

02:48:58

12 Answer: I don't recall that.

13 Question: Well, is that a concern? Do you recognize
14 that as a legitimate concern?

15 And your answer was: I do recognize that as a
16 legitimate concern.

02:49:12

17 That was your testimony, sir, on the date of this
18 deposition?

19 A. Yes.

20 Q. Now you were familiar with all of the bench testing --

02:49:37

21 MR. LOPEZ: You can take the deposition down, Greg.

22 BY MR. LOPEZ:

23 Q. You were familiar with all of the bench testing and the
24 animal testing that was done at NMT prior to the Asch study;
25 correct?

02:49:53

United States District Court

ROBERT M. CARR, JR. - Direct

1 A. I'm familiar with it, yes.

02:49:55

2 Q. And did you participate in some of that or at least help
3 guide some of it?

4 A. I didn't perform I don't think any of it personally but I
5 was around and certainly knew what was happening.

02:50:08

6 Q. And all that testing that was designed by NMT was to try
7 to mimic what might happen in the human body had that device
8 been exposed to a real vena cava in a real human being; true?

9 A. Partially. The goal of all of the testing is to both
10 satisfy the requirements from a regulatory point of view as
11 well as do your best to mimic the first physiological
12 conditions that the device would be under.

02:50:41

13 Q. Well, isn't the most important of those two things is to
14 mimic a human being to make sure that you minimize the
15 potential risk of actually putting that device in a human
16 being? That's the most important thing about bench testing and
17 animal testing, wouldn't you agree?

02:51:01

18 A. To the best of your ability, yes.

19 Q. Right. And then once you do the -- you put it in a human
20 being for the first time when you only know how it's working on
21 a workbench with respect to something like migration, the
22 patients need to be very closely monitored; right?

02:51:18

23 A. In clinical trials the patients are monitored.

24 Q. And we're talking about the Asch study with respect to the
25 Recovery; correct?

02:51:37

United States District Court

ROBERT M. CARR, JR. - Direct

1 A. In general.

02:51:39

2 Q. Well, I know I want to talk about just this device and
3 this study by now. In the Asch study, the bench testing and
4 the animal testing suggested to you that the Recovery filter
5 could resist migration and could actually resist fracturing in
6 a human being; true?

02:51:54

7 A. The migration resistance has a specification which is 50
8 millimeters of mercury so it's tested to be able to resist that
9 on average.

10 With respect to fracture, that's also a test that is
11 done on the bench and that is taken to an equivalent of ten
12 years life cycle is how it's tested. I believe they all
13 eventually would break.

02:52:14

14 Q. Well, I'm not sure you answered my question. My question
15 was a lot simpler than that and that is that the bench testing
16 results that you got for migration resistance and fracture,
17 based on the parameters of the testing, were suggested to you
18 that if this device were put in a human being, that it would
19 not break and it would not migrate; true?

02:52:33

20 A. No, that's not true.

02:52:54

21 Q. So you did a pilot study and put them in human beings
22 without any assurances or at least some indication from your
23 bench testing and your animal testing that this device would
24 not migrate or fracture?

25 A. No. We never did a pilot study and that's why I explained 02:53:12

ROBERT M. CARR, JR. - Direct

1 what we did in both the migration and the fracture test.

02:53:16

2 Q. Okay. How did you convince Dr. Asch to actually implant
3 these in patients unless you had some preclinical studies that
4 suggested that it was safe to implant these in a human being?

5 A. We had bench testing and animal testing.

02:53:34

6 Q. Okay. That's what I thought. And once you did the Asch
7 study and you saw that one and only patient that got challenged
8 by a clot of any significance, that the device migrated and in
9 the first 33 patients you had a double fracture, did that tell
10 you or anyone at NMT or Bard that maybe you ought to reconsider
11 the way you're bench and animal testing the Recovery filter?
12 Can you answer that yes or no?

02:53:55

13 A. I don't think I can answer it yes or no.

14 Q. I mean, I think you might if you try and that is if the --
15 was there anything about the results of the Asch study? In
16 other words, there was a migration with a clot challenge and
17 there was a fracture of a foot and a leg. Did that suggest to
18 you that maybe your animal testing and/or bench testing might
19 not be sufficient to predict what would happen in a human being
20 when it comes to migrations and fractures?

02:54:16

02:54:35

21 A. No, I don't remember that, no.

22 Q. So you didn't learn anything from the Asch study with
23 respect to your bench testing and your animal testing?

24 A. Yes.

25 Q. Were you satisfied that your animal testing and your bench

02:54:53

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1 testing was sufficient to predict what was going to happen in 02:54:56
2 humans after you got the results from patient nine and patient
3 32 from the Asch study?

4 A. Yes.

5 Q. Let me have exhibit I think it's 800. 02:55:19

6 Sir, your counsel were provided with a number of
7 documents that we might use today and I believe this was one of
8 them, so did you have a chance to review this before you came
9 to court today, the Exhibit 800?

10 A. Yes. 02:55:51

11 Q. And I just want you to look at -- first of all, this is
12 dated January 13, 1993; correct?

13 A. No.

14 Q. I'm sorry. 1998. And your name is on there, Rob Carr.

15 A. Yes. 02:56:05

16 Q. And we go down to number three, literature review. Who is
17 Thom Kinst?

18 A. Thom was a marketing person at NMT.

19 Q. And Thom Kinst reports --

20 MR. LOPEZ: Your Honor, I would like to offer this 02:56:26
21 Exhibit 800 into evidence, please.

22 MR. NORTH: No objection, Your Honor.

23 THE COURT: 800 is admitted.

24 (Exhibit Number 800 was admitted into evidence.)

25 MR. LOPEZ: May I publish to the jury? 02:56:35

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1 THE COURT: Yes.

02:56:37

2 BY MR. LOPEZ:

3 Q. And Thom Kinst -- or at least this memo reports that he
4 spent a day at the Countway Library digging out papers that
5 help answer the question, quote, how high can the pressure drop
6 across the filter be immediately post occlusion, end quote.

02:56:49

7 Do you see that, Mr. Carr?

8 A. Yes.

9 Q. And then: Steve has made a preliminary review of the
10 papers retrieved. And the data in those papers pushes us to
11 assume that the delta P-- what is delta P?

02:57:05

12 A. The pressure.

13 Q. -- could certainly be 50 millimeters of mercury; some
14 references indicate that even higher pressures might occur in
15 certain circumstances.

02:57:26

16 Do you see that, sir?

17 A. I do.

18 Q. And for purposes of your determining a threshold starting
19 point in testing migration resistance on the bench at least at
20 NMT and some of the early tests you did at Bard was to assume
21 that that number was 35; correct?

02:57:40

22 A. Through our conversations with physicians, the number that
23 was -- came to was 35, yes.

24 MR. LOPEZ: Can I have 1452, please. Actually. We
25 should start with -- let's start with 1452.

02:58:14

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1 BY MR. LOPEZ:

02:58:20

2 Q. Sir, are you familiar with this document?

3 A. I saw it yesterday.

4 Q. Are these notes from a meeting that you had with
5 Dr. Kaufman, Dr. Venbrux and an attorney Howard Holstein?

02:58:32

6 A. They appear to be but I don't know whose notes these are.

7 Q. You've never seen these notes before?

8 A. I saw them yesterday.

9 Q. For the first time?

10 A. No. But I don't know whose they are.

02:58:45

11 Q. Well, if you go down to the bottom -- you were at this
12 meeting; correct?

13 A. It says I have a quote at the bottom of the meeting, yes,
14 but I don't recall this meeting.

15 Q. Okay. Okay. And let me -- you don't know whose notes
16 these are?

02:58:56

17 A. I don't know whose notes they are, no.

18 Q. They are not your notes?

19 A. They are not.

20 Q. Do you remember when this meeting took place?

02:59:11

21 A. No, I don't.

22 Q. These were notes that were produced as part of this
23 litigation. Do you see the Bates numbers there at the bottom?

24 A. I do, yes.

25 MR. LOPEZ: I would like to offer 1452 into evidence

02:59:27

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1 at this time, Your Honor.

02:59:30

2 MR. NORTH: Objection, Your Honor. 802.

3 THE COURT: Sustained.

4 BY MR. LOPEZ:

5 Q. Okay. Now, sir, you remember being at a meeting with
6 these three individuals; correct?

02:59:37

7 A. No, that's not correct.

8 Q. You are quoted there at the bottom. Do you see that?

9 A. I do see that.

10 Q. And do you have a recollection as to whether or not
11 Dr. Venbrux at that time said to you and others at this meeting
12 that you should consider a migration resistance threshold as
13 high as 140 millimeters of mercury? Does that refresh your
14 recollection?

02:59:55

15 A. No, it doesn't. When I read this yesterday is what
16 refreshed my recollection.

03:00:16

17 Q. Sir, you don't recall this exhibit being used in another
18 trial?

19 MR. NORTH: Objection, Your Honor. 402.

20 THE COURT: It's sustained.

03:00:32

21 And, Counsel, if you're going to refresh
22 recollection, don't read it to him. Have him read it, set it
23 aside and then ask him if his recollection is refreshed.

24 BY MR. LOPEZ:

25 Q. Sir, did Dr. Kaufman ever express to you or anyone in your 03:00:47

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1 presence that he felt that the Recovery filter was a, quote,
2 wimpy filter, end quote?

3 A. Yes.

4 Q. And, in fact, does this refresh your recollection that
5 that happened at the meeting --

6 THE COURT: Mr. Lopez, if you're going to refresh his
7 recollection, have him read the document and then set it aside
8 and ask him if his recollection is refreshed. Don't read him
9 the document or the statements in the document.

10 BY MR. LOPEZ:

11 Q. And did you recall Dr. Venbrux, and maybe many of these
12 other doctors that you consulted with, that they felt that the
13 issue should be stability with the Recovery filter, not
14 retrievability early in its marketing?

15 A. I don't remember other people saying that. No,
16 Dr. Venbrux did. It's in this note here.

17 Q. And did that help refresh your recollection that he said
18 that?

19 A. No, it doesn't, sir. I don't recall the meeting.

20 Q. And then let's look at Exhibit 1033. Do you see that,
21 sir?

22 A. Excuse me. Can you make it wider on the screen?

23 Q. Wider?

24 A. Yeah.

25 Q. I'll tell you what. The part I'm going to read -- the

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1 part I'm going to draw your attention to is the from the middle 03:02:18
2 down. Is there anything in here, sir, that refreshes your
3 recollection that you were at a meeting with Drs. Venbrux,
4 Kaufman, and Attorney Howard Holstein?

5 A. No. 03:02:37

6 Q. Did you discuss in the early part of 2004, after the
7 Recovery filter was on the market for a short period of time,
8 some of the problems that Bard was experiencing with the
9 Recovery filter with John Kaufman and Anthony Venbrux and an
10 attorney? 03:03:02

11 THE COURT: He's calling for your recollection, sir,
12 not what the document says.

13 THE WITNESS: I don't recall this meeting but I am
14 sure that I had conversations with John Kaufman and Tony
15 Venbrux about the Recovery filter. 03:03:14

16 BY MR. LOPEZ:

17 Q. Did John Kaufman or any of the people at the meeting
18 suggest that the arm fractures were associated with a, quote,
19 caudal shift, close quote?

20 MR. NORTH: Objection, Your Honor. 03:03:29

21 THE COURT: Mr. Lopez, would you approach, please.
22 Ladies and gentlemen, if you want to stand up, feel
23 free.

24 (Counsel meet at sidebar, 3:03.)

25 THE COURT: That's the third time you've done it. 03:03:41

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1 I've told you not to read from a document that is not in
2 evidence to refresh his recollection.

03:03:43

3 MR. LOPEZ: I understand, Your Honor. I know that.
4 I'm asking the question from the document.

5 THE COURT: You can't do that if it's not in
6 evidence. What you can do is you can show him the document,
7 have him set aside, ask, "Does it refresh your recollection
8 about a meeting?" You asked him that and he said no and so
9 then you read a quote from the document. You can't do that.

03:04:14

10 MR. LOPEZ: What's happening if he's looking at the
11 screen, if he would just look at me.

03:04:21

12 THE COURT: Well, let's do it in paper form or take
13 it off the screen. But don't quote and you even put it in
14 quotes that third time. Quote. You can't do that. So if you
15 want to refresh his recollection, and this goes for both sides,
16 have him look at the document, set it aside, have him look back
17 at you or get it off the screen and ask, "Does that refresh
18 your recollection?" And if yes, you can ask him questions
19 about the recollection.

03:04:27

20 MR. LOPEZ: This is a company document. This
21 document are notes that were kept in the ordinary course of
22 business. Mr. Carr is quoted on this. This should be an
23 exception to the hearsay Rule under 801 -- whatever it is.
24 These are declarations against interest. These are admissions.

03:04:43

25 THE COURT: What you have to do in order to get this

03:05:05

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1 in under 801(d)(1)(A) is you have to present evidence that the
2 document is a document created by the company that the person
3 who is quoted was authorized to act as an agent for the
4 company. And if you're going to do it without a witness, you
5 have to do it with the contents of the document. It can work
6 with the memo or it's a Bard letterhead and a VP writing.

7 Handwritten notes, I can't look at those notes and
8 say, "Yeah, it's evident from looking at the document that it's
9 either a Bard document or by an authorized witness." But let's
10 argue about this after the jury is not waiting.

11 I'm not going to rule in your favor on this at this
12 point. I'll be happy to hear your argument but I don't want to
13 keep the jury waiting on the 801(d)(2)(A). I just want to make
14 sure that we're square on the procedure for refreshing memory.

15 MR. LOPEZ: I understand. I apologize. I didn't do
16 that on purpose.

17 THE COURT: Okay. That's fine.

18 (End of sidebar discussion.)

19 THE COURT: Thanks, ladies and gentlemen.

20 BY MR. LOPEZ:

21 Q. Sir, I'm going put a transcript in front of you from a
22 proceeding that happened about three years ago. Do you have
23 that in front of you?

24 A. I have something in front of me, yes. I don't know what
25 it is.

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1 Q. Well, I'm not -- I don't know. I'm not supposed to say.
2 So it's a transcript where you were testifying under oath.
3 Okay?

4 A. Yes.

5 Q. And you said that the first time you saw that document was
6 yesterday; correct?

7 A. Yes.

8 Q. And do you see here -- does this help refresh your
9 recollection that not only did you see it before yesterday, but
10 you actually testified about it three years ago?

11 A. No. I had seen a different version of that document with
12 notes on it.

13 Q. So you had seen this document before with notes on it?

14 A. With notes on it, yes.

15 Q. Okay. Were those notes your notes?

16 THE COURT: Excuse me. Mr. Carr, when he's asking
17 you a question and you're reading what's on the screen, he'll
18 tell you to do that when he needs you to do that.

19 He wants you to testify from your memory.

20 THE WITNESS: Okay.

21 BY MR. LOPEZ:

22 Q. You were asked at this proceeding, sir, look at 187, line
23 five: Did anyone ever raise a concern to you that the device
24 had an inadequate radial force level and that was resulting in
25 migration of the filter?

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1 And you answered: We certainly talked about that
2 with Dr. Kaufman and others, yes.

03:08:44

3 And the question: And they told you it was a wimpy
4 filter?

5 And you answered: It feels wimpy in air, yes.

03:08:54

6 Question: And its radial force was inadequate to
7 prevent migration?

8 Answer: I think they were concerned about it. They
9 didn't say it was inadequate.

10 Question: They also told you your migration
11 resistance specification was inadequate to prevent migration as
12 well, correct?

03:09:08

13 Answer: I think they said we needed to look at it
14 and address it.

15 Question: And they suggested raising it to 140
16 millimeters of mercury; is that right.

03:09:21

17 Answer: I believe Dr. Venbrux put out 140 as a
18 number, yes.

19 Question: Remind me, what was it before, 50?

20 Answer: It is 50, yes.

03:09:40

21 Sir, does that help refresh your recollection that
22 yesterday was not the first time that you saw the contents and
23 the notes from a meeting that happened in 2004 with the three
24 individuals I had previously identified?

25 A. Yes.

03:09:59

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1 Q. And the notes that we have been going back on, those are
2 the notes; right?

03:10:01

3 A. They appear to be the notes, yes.

4 MR. LOPEZ: Your Honor, now I would like to offer
5 1452 and 1033 into evidence.

03:10:09

6 MR. NORTH: Objection. 802. All he said is --

7 THE COURT: You don't need to argue it. Sustained.
8 It's still hearsay even if he remembers it.

9 MR. LOPEZ: Okay.

10 BY MR. LOPEZ:

03:10:24

11 Q. But for sure yesterday was not the first day that you saw
12 those notes; true?

13 A. I said I saw a different version.

14 Q. Did you bring that version with you by any chance, the
15 different version?

03:10:38

16 A. No, I didn't bring anything with me.

17 Q. Okay.

18 MR. LOPEZ: Can we put 4327 up, please.

19 Your Honor, this is going to be 4337 with the
20 additional material that was removed from -- I'm not sure it
21 was officially removed from the exhibit, trial exhibit, or not
22 or whether or not we're reserving on that. I won't go into the
23 back part --

03:11:13

24 THE COURT: This is the one where we admitted seven
25 pages?

03:11:28

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1 MR. LOPEZ: Yes, Your Honor. 03:11:31

2 THE COURT: Okay. You said 4337. I think it says
3 4327.

4 MR. LOPEZ: It says 4327.

5 THE COURT: Right. And I have looked, by the way, at 03:11:38
6 the last three pages and I think they are clearly hearsay
7 within hearsay. So I'm standing on my ruling that the first
8 seven pages are admitted but not the last three.

9 MR. LOPEZ: I understand, Your Honor.

10 BY MR. LOPEZ: 03:11:49

11 Q. Now, sir, I want you to look at 4327. We can show you.

12 MR. LOPEZ: And may I publish this to the jury, Your
13 Honor?

14 THE COURT: You may.

15 BY MR. LOPEZ: 03:12:01

16 Q. And this is a monthly global PV report. Do you see that?

17 A. Yes.

18 Q. Do you know what a monthly global PV report is?

19 A. It looks like John McDermott's monthly report to
20 corporate. 03:12:16

21 Q. And did you, as a matter of course, get copies of these
22 reports and their attachments?

23 A. No.

24 Q. Can we look at page four of the exhibit? I have Chris
25 Ganser highlighted on there because that's from another 03:12:39

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1 deposition; but if you look at the left, you're listed as
2 having been copied on this report. Do you see that?

3 A. I do.

4 Q. Does that refresh your recollection that you were one of
5 the recipients of these monthly reports?

6 A. I don't see a cc list but I will accept that.

7 Q. Well, let's go down to -- let's go to the bottom of page
8 three of the exhibit and you'll see what happens. They start
9 the cc list there at the bottom. Do you see?

10 A. Yes.

11 Q. And then you go to the next page and it carries over in
12 four columns just like was started on page three.

13 A. Yes.

14 Q. So you were someone who would get copies of these monthly
15 reports; right?

16 A. I got this one.

17 Q. By the way, what does PV stand for?

18 A. Peripheral vascular.

19 Q. Okay. And as part of those monthly reports, would you get
20 what are known as MDR reports?

21 A. I don't recall these reports so you would have to show me
22 the content.

23 Q. Okay.

24 MR. LOPEZ: Don't take it down, Greg, from showing it
25 to the jury.

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1 And show Mr. Carr page eight. 03:14:03

2 THE COURT: Are you doing this to refresh his
3 recollection?

4 MR. LOPEZ: Hopefully to lay a foundation, Your
5 Honor. He's a recipient of this monthly report. 03:14:14

6 BY MR. LOPEZ:

7 Q. So, sir, you see this. Is there anything on there that
8 looks familiar to you like something you would receive in
9 monitoring the adverse events and the complications with the
10 IVC filters? 03:14:44

11 A. Again, I don't recall receiving these. It's a long time
12 ago but it seems like a list of complications for the filter.

13 THE COURT: Excuse me, sir. He's just asking if you
14 remember it, not to describe it.

15 THE WITNESS: No, I don't remember. 03:15:05

16 BY MR. LOPEZ:

17 Q. So you don't remember going to -- getting a monthly report
18 where you were kept apprised of the reports of injuries and
19 malfunctions and complications with the products that you were
20 working with? 03:15:22

21 A. I don't remember receiving his report, no.

22 Q. But you're certainly on here as someone who has received
23 copies of these; true?

24 A. Of this one, yes.

25 Q. And, sir, as an engineer, wouldn't it have been important 03:15:33

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1 for you to have been kept apprised of the ongoing trending and
2 injuries that were associated with the Recovery and G2 filter
3 during this period of time?

03:15:36

4 A. And I believe I was but through different mechanisms.

5 MR. LOPEZ: Your Honor, I would still like to offer
6 this into evidence at this time in its entirety.

03:15:54

7 THE COURT: The last three pages?

8 MR. LOPEZ: Yes, Your Honor.

9 MR. NORTH: Same objection, Your Honor. Multiple
10 layers.

03:16:03

11 THE COURT: All right. Sustained on hearsay grounds
12 on last three pages.

13 BY MR. LOPEZ:

14 Q. Well, when you were having problems in the early first few
15 months of the G2 Filter being on the market, I think you told
16 us that you kept pretty close attention to those reports; true?

03:16:20

17 A. When we were having problems in the first few months?

18 Q. Yes.

19 A. I don't know what you're referring to.

20 Q. You don't know what I'm referring to?

03:16:36

21 MR. LOPEZ: Could you put that back up, Greg, and see
22 if this helps refresh your recollection about those problems.
23 And go to page seven. I'm sorry, page eight.

24 Q. Can you look at the screen, sir? And I just want to ask
25 you if this helps refresh your recollection about the number

03:17:05

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1 and type of adverse events that Bard had experienced as of the
2 date of this monthly report, February 10, 2006.

3 THE COURT: So he's asking you to look at the
4 document, then look back at him and tell him whether that
5 refreshes your recollection on those problems.

6 THE WITNESS: Does it refresh my recollection? Yes,
7 these are reported complaints and a list of the number of
8 events.

9 BY MR. LOPEZ:

10 Q. Okay. And something that, in your regular and ordinary
11 course of business, the type of information you would review to
12 keep up with how the product was performing in the field?

13 A. Yes, again, but I did it in a different mechanism. I
14 don't remember these monthly reports.

15 Q. Now, let's talk about the EVEREST study. Could you tell
16 the Court and the jury what the EVEREST study is or was?

17 A. It was a clinical trial for -- to get removability for the
18 G2 filter.

19 Q. And when did the EVEREST study start? When did you
20 actually start implanting patients with the G2 filter to see if
21 it could be retrieved?

22 A. I don't know the specific date but I would say late 2005.

23 Q. Okay. The G2 filter was cleared as a permanent filter
24 sometime around September of 2005?

25 A. Again, I'm bad with the dates but that sounds about right,

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1 yes.

03:19:02

2 Q. And then it was decided that because it was a permanent
3 filter, you needed to do a retrievability study to see if you
4 could get an indication to have this permanent device also be a
5 retrievable device?

03:19:17

6 A. Yes, but I wouldn't say it that way. It was always
7 designed as an optional device and our original submission was
8 to have it approved as an optional device. And the FDA asked
9 us to do a trial for removability, but they granted it as a
10 permanent device first.

03:19:37

11 Q. So we're talking about December 2005. It was already --
12 the company was already receiving reports that it had caudal
13 migrations and perforations and some problems with the device
14 in the first three or four months it was on the market;
15 correct?

03:19:56

16 A. That report is from January of '06 so I guess so, yes.

17 Q. Okay. And the company had determined that they probably
18 should be putting caudal anchors to eliminate the caudal
19 migration and tilting they were experiencing early in the
20 marketing of the device; correct?

03:20:14

21 A. I don't know that, no.

22 Q. Let's look at your deposition on April 17, 2013?

23 MR. LOPEZ: Greg, can you put that on the screen?

24 Page 93.

25 \\

ROBERT M. CARR, JR. - Direct

1 BY MR. LOPEZ:

03:20:43

2 Q. Do you see where I am?

3 A. I see the page.

4 Q. And I want you to look at line 11 and I'll read this
5 question -- question and your answer:

03:20:49

6 The field and our clinical data have shown an
7 increased frequency of migration in the caudal direction with
8 the G2 and the G2 Express filters as compared to Recovery.

9 Now, were you familiar with that clinical data that's
10 being referenced there?

03:21:06

11 Answer: Yes.

12 Question: The application of caudal anchors would
13 potentially eliminate this failure mode to reduce tilting of
14 the filter.

15 You answered: I believe it says and reduce tilting
16 of the filter.

03:21:15

17 Question: And reduce tilting of the filter.

18 Now, was this anchor system ultimately implemented?

19 Answer: Yes.

20 Next page, please. And how would this anchoring
21 system reduce tilting of the filter?

03:21:26

22 If the filter can't move, it can't tilt.

23 That was your answer when this deposition was taken
24 in April of 2017. True, sir?

25 A. My answer to your original question, no.

03:21:45

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ROBERT M. CARR, JR. - Direct

1 Q. No. This was your testimony on that day?

03:21:47

2 A. But you asked a different question, sorry.

3 Q. So you know who Natalie Wong is; right?

4 A. I do.

5 Q. And you know that she conducted what's called -- known as
6 a DFMEA with respect to the caudal migrations that the company
7 was experiencing in the first five to six months it was on the
8 market; true?

03:22:04

9 A. I don't know the timing of it, no.

10 Q. But you know that there was -- I want you to assume that
11 in March that Natalie Wong had conducted a DFMEA on caudal
12 migrations and she determined through that analysis that the G2
13 presented an unacceptable risk of caudal migration and the more
14 serious category and injury numbers for that type of an event.
15 Can you assume that for me?

03:22:19

03:22:44

16 A. No. If you show to it me, I'll read it.

17 Q. Okay.

18 MR. LOPEZ: This has been admitted, Your Honor.

19 THE COURT: What has?

20 MR. LOPEZ: 2248.

03:23:32

21 THE COURT: Let me see if Traci agrees.

22 COURTROOM DEPUTY: Yes, it's been admitted.

23 MR. LOPEZ: May I publish, Your Honor?

24 THE COURT: You may.

25 \\

ROBERT M. CARR, JR. - Direct

1 BY MR. LOPEZ:

03:23:47

2 Q. Sir, do you see that this document is dated March 2, 2006;
3 correct?

4 A. Yes.

5 Q. And attached to this is a G2 caudal report PowerPoint.
6 Have you not seen this before?

03:23:53

7 A. If you show it to me, I can tell you.

8 MR. LOPEZ: Can we go to the page that has the
9 unacceptable risk?

10 Q. Do you see that, sir?

03:24:17

11 A. Yes.

12 Q. And do you see where be this DFMEA determined that for
13 caudal threshold, the G2 posed an unacceptable risk for Type
14 III above threshold. Do you see that?

15 A. Yes.

03:24:41

16 Q. And that was as a permanent device; correct?

17 A. Yes.

18 Q. And the company was already discussing at this period of
19 time that they needed to make some design changes to the G2 to
20 correct its caudal migration problem. Do you remember that?

03:24:56

21 A. No, I don't.

22 Q. So the EVEREST study, this study was actually conducted,
23 continued to be conducted after what we just discussed with
24 respect to this March 2006 DFMEA and the fact that the company
25 had determined that they had some trending going in the bad

03:25:26

ROBERT M. CARR, JR. - Direct

1 direction with respect to caudal migration; correct?

03:25:30

2 A. I would not put it that way. I would put it that the Quad
3 Level 3 here, there's a description at the bottom that says you
4 need recommended actions prior to product release. But this is
5 after the product had been released.

03:25:48

6 Q. Right. In other words, if this product hadn't been
7 released, this DFMEA is telling the company, "Don't release it
8 yet until we take care of the problem"; right?

9 A. This document says that you would need to put controls in
10 place to reduce that observation level, yes.

03:26:04

11 Q. Controls would include looking the design of the device,
12 maybe retesting it to see what might be wrong with the device
13 to see if this unacceptable risk issue could be resolved?

14 A. Verification testing usually, yes.

15 Q. But that wasn't done in response to this; correct?

03:26:27

16 A. I don't know.

17 Q. All right. So EVEREST -- so what we have here is the
18 company, as a permanent device, had made a determination, at
19 least according to this DFMEA, that there was an unacceptable
20 risk of caudal threshold and they were now conducting a
21 retrievability study on the same device?

03:26:44

22 A. Yes, but this FMEA -- the FMEA is a living document. It
23 changes over time so when we observed these complaints coming
24 in, this is an update to our DFMEA at the time and there were
25 no controls for that complication because we hadn't seen it

03:27:06

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ROBERT M. CARR, JR. - Direct

1 before.

03:27:09

2 Q. And what didn't change, the discussion in the company that
3 there had to be some design changes made to the G2 to deal with
4 the caudal migration, namely the caudal anchor; true?

5 A. Ultimately, those conversations were had and that change
6 was made, yes.

03:27:24

7 MR. LOPEZ: Can we have 4327, please, back up again
8 and let's look at page -- let's look at page five of the
9 exhibit.

10 I would like to publish this to the jury, Your Honor.

03:28:03

11 THE COURT: You may.

12 BY MR. LOPEZ:

13 Q. Do you see this? Do you see what I'm showing you, what's
14 highlighted there?

15 A. Yes.

03:28:09

16 Q. So the team was already embarking on trying to figure out
17 through design changes the caudal migration issue with the G2
18 filter; right?

19 A. Yes.

20 Q. Were the subjects of the EVEREST trial, meaning the
21 clinical trial subjects, advised that this was going on before
22 they agreed to participate in the EVEREST trial? In other
23 words, were they told that we have a design issue we're trying
24 to resolve?

03:28:28

25 A. I don't know.

03:28:46

United States District Court

ROBERT M. CARR, JR. - Direct

1 Q. And the reason that you did the EVEREST trial and
2 continued the EVEREST trial after some of this evidence we've
3 seen was the caudal migration and the design issues was to get
4 an indication for retrievability; right?

5 A. Yes.

6 Q. Because retrievability would open up an opportunity to
7 expand the marketability of the G2; true?

8 A. All filters that we were designing at the time were
9 intended to be optional and I think as I stated before, the
10 initial intent of this device was for it to be optional from
11 the start. So the permanent to removable pathway became a
12 regulatory process, not our business intent.

13 Q. Let me ask it a different way. While this device only had
14 an indication as a permanent device, the company was precluded
15 from marketing it as a retrievable device; true?

16 A. Yes. We could not promote it as a retrievable device.

17 Q. And you couldn't do that until you got retrievability in
18 2008; correct?

19 A. I don't know the time but until we got approval, yes.

20 Q. And in order to get clearance to market this device as a
21 retrievable device, you had to complete the EVEREST trial;
22 right?

23 A. In addition to all our other testing, yes.

24 Q. And this EVEREST trial was going on while the company was
25 looking at how they were going to fix the caudal migration

United States District Court

ROBERT M. CARR, JR. - Direct

1 perforation and tilt problems with the G2?

03:30:23

2 A. We were looking at how to improve the performance of the
3 device.

4 Q. And you already had signals from what doctors were
5 reporting to you about these issues of caudal migration, tilt,
6 perforation, sometimes those three things in the same patient,
7 you were already getting reports of that in early part of 2006;
8 correct?

03:30:34

9 A. I don't know that, no.

10 Q. Well, can you already have reports and complaints of the
11 G2 filter having all of those things and even including a
12 fracture that was caught was causing the device to migrate and
13 embolize in the vena cava?

03:30:51

14 A. No, I don't know that.

15 Q. And you were in charge of the G2 and the EVEREST study;
16 right?

03:31:15

17 A. No, I was not in charge of the EVEREST study.

18 Q. Didn't you say you were the one that recruited all the
19 doctors and you helped set the whole thing up?

20 A. Yes, I helped but I was not in charge of the study.

03:31:29

21 Q. Can we look -- well, you recruited Dr. Venbrux and
22 Dr. Kaufman; right?

23 A. They were people we worked with at the time so I don't
24 think it took much of a recruiting effort.

25 Q. Now, as part of the EVEREST study, these individuals were

03:31:52

United States District Court

ROBERT M. CARR, JR. - Direct

1 only to be in the study for, what, 180 days? There was
2 supposed to be retrievability within 180 days and thereafter it
3 would become a permanent device?

03:31:59

4 A. I would have to see the protocol. I haven't read it in a
5 long time.

03:32:12

6 Q. You didn't know we were going to be talking about the
7 EVEREST trial today?

8 A. Not in particular, no.

9 Q. And even though the EVEREST trial was a trial for
10 retrievability just as part of the protocol, just like in the
11 Dr. Asch study, the patients would be medically monitored for
12 complications; true?

03:32:32

13 A. Again, I would have to see the protocol to know what it
14 said.

15 Q. All right. Let's look at Exhibit 422. Is this the final
16 study report for the EVEREST trial exhibit that you have up
17 there right now?

03:32:46

18 A. It's the title. I don't know if it's a draft or the final
19 one.

20 Q. Let's look at 1517, please.

03:33:41

21 Sir, are you familiar with this document?

22 A. No.

23 Q. You've never seen it before?

24 A. I don't recall it, no.

25 Q. Do you see at the bottom of this document that it states

03:34:08

United States District Court

ROBERT M. CARR, JR. - Direct

1 that it is the property of C.R. Bard, Inc.?

03:34:10

2 A. I do.

3 Q. That's the company that you worked for while the EVEREST
4 study was going on?

5 A. Yes.

03:34:23

6 Q. And it also has the logo on some of these pages. If you
7 go to page -- let's just randomly go to page 38 and tell me
8 whether or not that has the Bard Peripheral Vascular logo on
9 it.

10 A. I don't have it yet. Sorry. Yes, I do see it.

03:34:51

11 MR. LOPEZ: Your Honor, I would like to offer this
12 Exhibit 1517 into evidence right now.

13 MR. NORTH: No objection, Your Honor.

14 THE COURT: 1517 is admitted.

15 (Exhibit Number 1517 was admitted into evidence.)

03:35:07

16 BY MR. LOPEZ:

17 Q. Did you, sir, closely monitor the results of the EVEREST
18 trial as it was going on?

19 A. No.

20 Q. You didn't pay close attention to the adverse events
21 that --

03:35:22

22 A. No. I had a different responsibility during the tail end
23 of the EVEREST trial and the data was not disseminated widely.

24 Q. All right. The trials took place in 2006 and 2007. Do
25 you recall that?

03:36:12

United States District Court

ROBERT M. CARR, JR. - Direct

1 A. I thought 2005 so I don't know the time frame.

03:36:14

2 MR. LOPEZ: Let's look at Trial Exhibit 1517. And I
3 would like to show this to the jury, Your Honor.

4 THE COURT: You may.

5 MR. LOPEZ: Go to the first page, Greg, please.

03:36:28

6 BY MR. LOPEZ:

7 Q. Do you see, sir, that this is -- the subject of this
8 PowerPoint presentation is EVEREST and TrackWise Data Review?

9 A. This is the same document you just showed me?

10 Q. Yes.

03:36:52

11 A. Sorry. I thought you changed. Yes.

12 Q. And did you participate in any meetings regarding the
13 EVEREST trial and the results?

14 A. I'm sure that I did.

15 Q. And do you recall going to a meeting where the EVEREST
16 results and the TrackWise data was discussed?

03:37:07

17 A. No.

18 Q. And you would agree with me that this is an official Bard
19 document that we're looking at?

20 A. I don't know what you mean by that but I have no reason to
21 doubt.

03:37:21

22 Q. For example at the bottom it says confidential: This
23 document contains information that is confidential and
24 proprietary property of C.R. Bard, Inc.

25 Do you see that?

03:37:31

United States District Court

ROBERT M. CARR, JR. - Direct

1 A. Yes.

03:37:32

2 Q. Okay. Now, page six. Actually, let's do this. Let's go
3 to paragraph -- I'm sorry, slide eight. We've already seen
4 some of this other stuff with another witness. And do you see
5 that this has a chart of the different complications that were
6 observed in the EVEREST trial?

03:38:22

7 A. Yes.

8 Q. Sometimes there were multiple complications in one
9 patient. For example, at the far right, caudal, fracture, tilt
10 and penetration?

03:38:38

11 A. Had happened in one patient, yes.

12 Q. And then in another patient, caudal, fracture, and
13 penetration without tilt.

14 A. Yes.

15 Q. Okay. Look at the next page of this PowerPoint. Do you
16 see that this is -- someone charted the migrations of all of
17 the devices that were implanted in this study? Do you see
18 that? Do you see those diamonds all over the place?

03:38:50

19 A. I see the diamonds but I haven't read the slide yet.

20 Q. Well, zero is where they would have implanted it; correct?

03:39:19

21 A. Give me a moment to read, please.

22 Q. Okay.

23 A. I'm sorry. Ask me again, please.

24 Q. Now, this is showing a diagram of the device and the
25 patients in this study and where the device was found in

03:39:43

United States District Court

ROBERT M. CARR, JR. - Direct

1 relationship to where it was implanted; correct? Do you see
2 the dark line?

3 A. Yes.

4 Q. And it looks like more than 50 percent of these -- we can
5 count them but I don't want to take the time to do that --
6 migrated more than one centimeter?

7 A. No, I don't believe that.

8 Q. Okay. Well, it's pretty clear -- if you just look at
9 this, you'll see that there were 50 that migrated somewhere
10 between zero and almost 20 millimeters.

11 A. Yes.

12 Q. And another 10 that went beyond 20 millimeters or beyond
13 two centimeters; right?

14 A. Which is what is considered migration, yes.

15 Q. I'm sorry which is considered migration.

16 A. Yes.

17 Q. Well, I understand that but doesn't this graph, just
18 looking at it, wouldn't this tell anybody, especially an
19 engineer, that we've got a stability problem with the G2 filter
20 from our one and only pilot clinical study that we did both
21 going up and going down?

22 A. No, it wouldn't.

23 Q. You don't -- do you have another comparison of another
24 study you did that would give us a better baseline as to
25 whether the device should have stayed in the middle?

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ROBERT M. CARR, JR. - Direct

1 A. To me the device did stay in the middle. Less than two
2 centimeters is not classified as a migration, so there's only
3 10 of these 81 I believe that we would term as migration.

03:41:19

4 Q. Well, I know that's the company's determination, right,
5 two centimeters?

03:41:34

6 A. Which has been accepted by the FDA since 1999 I believe or
7 2000.

8 Q. Well, in fact, the FDA guidance document calls it
9 migration, five millimeters, doesn't it?

10 A. The guidance document does call it migration at five
11 millimeters but, again, when we first spoke to the FDA
12 developing our specifications all the way back in either '99 or
13 2000, we had a conversation with them and decided --

03:41:48

14 MR. LOPEZ: Objection, Your Honor. Now, he's just
15 making a speech and it's hearsay.

03:42:10

16 THE COURT: Hold on just a minute. Well, I can't
17 read the question because my LiveNote is not up. I thought it
18 was responsive. So I'm going to let him finish.

19 MR. LOPEZ: I just asked him if in the guidance
20 document it said five millimeters.

03:42:25

21 THE COURT: No. You asked him what the FDA standard
22 was and I think he's now responding so I'm going to let him
23 finish the answer.

24 THE WITNESS: So back in our original conversations
25 with the FDA, we -- Dr. Kaufman and other, Dr. Simon, felt that

03:42:41

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ROBERT M. CARR, JR. - Direct

1 the specification should be two centimeters mostly due to the
2 ability to image accurately and that anything less than that
3 was due to either the patient's position or just other imaging
4 specificity.

03:42:48

5 So since that time, two centimeters has been our
6 specification and we have many submissions to the FDA where
7 they have concurred with that.

03:43:04

8 BY MR. LOPEZ:

9 Q. Okay. Now, let's just look at this slide. We don't have
10 to talk about the FDA or anything. Let's talk about what we're
11 seeing on this slide. What we know from this slide is that in
12 83 patients who only had this device in for 180 days or less,
13 there are a number of both cephalad and caudal migrations,
14 whether it's five millimeters, it's moving off the center line;
15 correct?

03:43:15

03:43:41

16 A. Again, no. You cannot say that it is moved less than that
17 number. You can't accurately determine how it's moved. That's
18 why the specification is two centimeters.

19 Q. Sir, I'm just talking about what's on this chart. You can
20 see -- we can all see what's on the chart; right?

03:43:57

21 A. We can.

22 Q. Now, these patients had this device in them for no more
23 than 180 days and the device was removed correct?

24 A. No, I don't think that's accurate.

25 Q. Let's assume that most of these people, the device was

03:44:12

ROBERT M. CARR, JR. - Direct

1 removed and this is how they found their device. Do we know
2 what these -- where these diamonds might have been in those
3 patients had the device stayed in them for another year or two
4 years or three years? Some of these people that are less than
5 two centimeter migrations. Any idea?

03:44:14

03:44:31

6 A. So I'm not going to assume that these devices were or were
7 not removed. It doesn't say it. You said that ten of these
8 devices have moved. That's what it says.

9 Q. All right. Now, do we know what happened to any of these
10 patients had they been followed and kept in this study for
11 another year or two years where these various diamonds might
12 have gone, any idea?

03:44:52

13 A. If they were removed, nowhere but I don't know.

14 Q. If they were kept in, we don't know, do we?

15 A. If we don't see it we can't know, no.

03:45:10

16 Q. And the study was not designed to follow patients into
17 longer periods of time, a year or two years or three years down
18 the road, to see what the migrations may have been with the G2
19 filter; true?

20 A. No. There was a period of time that they were followed
21 and I don't know it. I have to look at the protocol to see
22 where patients were followed. Every study is truncated at some
23 point.

03:45:25

24 Q. "Truncated" meaning at 180 days in the EVEREST study?

25 A. Again, I would need to look at the protocol to know.

03:45:41

United States District Court

ROBERT M. CARR, JR. - Direct

1 Q. "Truncated" meaning what, they stopped following the
2 patients?

03:45:44

3 A. Yes. Unless they came back for removal.

4 Q. Let's look at the next slide, number ten. This shows
5 filter penetrations and these are all patients in the pilot
6 study; right?

03:45:56

7 A. It's not a pilot study, first of all.

8 Q. I'm sorry, in a clinical study for retrievability. These
9 are the penetrations that are noted?

10 A. Can you go back so I can read the slide, please. Okay.

03:46:13

11 Q. And then someone plots in the next slide that filter tilts
12 in various IVC diameters, do you see that?

13 A. Yes.

14 Q. And then there's a summary on slide 14 of the
15 complications in EVEREST. The greatest number of complications
16 is associated with penetrations, 18 out of 83; followed by
17 tilts, 15 out of 83; caudal migrations, 10 out of 83, and a
18 single fracture. 80 percent of caudal migrations are
19 associated with other complications, namely tilt and
20 penetrations.

03:46:45

03:47:12

21 Did I read that correctly?

22 A. Yes.

23 Q. Meaning that if you had caudal migration, there was a
24 pretty strong connection to tilt and penetrations; true?

25 A. I think either, not both.

03:47:29

United States District Court

ROBERT M. CARR, JR. - Direct

1 Q. Okay. If you look at -- there's another slide. We went
2 over this slide with Mr. Randall. Now, was there a medical
3 monitor that was assigned to keep track of all of these so that
4 this information could be included in the company's evaluation
5 of this device's safety and effectiveness?

03:47:31

6 A. Yes, in all clinical trials.

7 Q. Was that Dr. Kris Kandarpa?

8 A. I think so, yes.

9 Q. Do you know Dr. Kandarpa?

10 A. No, I don't.

03:48:03

11 Q. Do you know that he was the one in charge of actually
12 monitoring these devices -- I'm sorry, monitoring the patients
13 and making sure that the patients were appropriately monitored
14 and that if there was a reason to stop the study, he could be
15 in a position to do that; right?

03:48:18

16 A. There's a Safety Monitoring Board which he was the chair
17 of I believe.

18 Q. All right.

19 A. So not just him.

20 Q. And did the company get monthly or periodic medical
21 monitoring minutes?

03:48:35

22 A. I don't know.

23 MR. LOPEZ: Could we show Exhibit 704, please, just
24 to the witness.

03:48:44

25 \\

ROBERT M. CARR, JR. - Direct

1 BY MR. LOPEZ:

03:49:22

2 Q. Now, Mr. Carr, you've seen the adjudicated data from the
3 medical monitoring data service involved in this clinical
4 trial, haven't you?

5 A. I've seen the final report, if that's what you're
6 referring to, of the clinical study.

03:49:31

7 Q. Okay. Will you look at your deposition that was taken on
8 March 4, 2010, page 116? Do you have that in front of you?

9 A. I have page 116 in front of me.

10 Q. Did you see any reports that indicated any possible
11 solutions to the tilting and penetration and you were asked
12 within the trial and your answer was no.

03:50:09

13 Of those three cases in the trial -- question: Do
14 you know if any such report was generated that would go through
15 the possible causes and possible solutions?

03:50:24

16 Your answer was: No.

17 Are you saying you don't know one way or the other?

18 Answer: No, I don't know that would -- there
19 wouldn't be a report on causes and solutions.

20 Why not?

03:50:39

21 Answer: Because it's a clinical trial and an
22 individual case report. So what happened is reported and
23 whatever knowledge a physician had of that patient would be
24 documented there.

25 Question: Would you go to research and development

03:50:50

United States District Court

ROBERT M. CARR, JR. - Direct

1 so that these events could be taken into consideration?

03:50:53

2 Answer: Of course. I'm aware of the trial.

3 Question. And how were you made aware of it, by an
4 email? By a letter? By just actually getting the clinical
5 trial report on the individual subject? Or just how did you
6 come about to know of it?

03:51:05

7 Answer: I don't know that I've seen the individual
8 patient report. I've seen the adjudicated data from the
9 medical monitor data service that does the -- takes all the
10 data in and generates the clinical report, which we then use to
11 file in our 510(k) with the FDA to get removal indication. So
12 through that review, through the filing of the 510(k) is when I
13 was -- and then you were asked: This would be a filing of the
14 510(k) after 2005; is that right?

03:51:25

15 And you said: Correct.

03:51:43

16 So does this refresh your recollection, sir, that you
17 actually were getting -- you were in communication with the
18 medical monitor and actually looking at these reports that were
19 being generated?

20 A. Absolutely not. I've never spoken to the medical monitor
21 or been involved in those communications. As I said earlier, I
22 did read the final study report.

03:51:55

23 Q. Okay. You said I've seen -- I've seen the adjudicated
24 data from the medical monitor data service?

25 A. Which is the data included in the study report.

03:52:11

United States District Court

ROBERT M. CARR, JR. - Direct

1 Q. Okay. And was that company that provided data service
2 BBA, known as BBA in Northborough, Massachusetts?

3 A. I don't know BBA.

4 Q. But you do know Dr. Krishna Kandarpa?

5 A. No, I don't.

6 Q. But you know that he was the medical monitor; correct?

7 A. Yes.

8 Q. And that he provided reports -- well, at the time he was
9 acting on behalf as an agent of Bard for purposes of monitoring
10 the patients and reporting to Bard his findings; true?

11 A. I have no idea.

12 Q. You really have no idea?

13 A. I really have no idea.

14 Q. But you know who Dr. Kris Kandarpa is?

15 A. I just said I don't.

16 Q. I thought you said earlier that you knew who he was.

17 A. No, I didn't.

18 MR. LOPEZ: Your Honor, I would like to show Mr. Carr
19 Exhibit 704.

20 BY MR. LOPEZ:

21 Q. Do you know who Elizabeth Rutter is?

22 A. No, I don't think so.

23 Q. Do you recognize any of the names on this exhibit?

24 A. Kris Kandarpa.

25 Q. I thought you said --

ROBERT M. CARR, JR. - Direct

1 A. We've just been speaking about him.

03:53:34

2 Q. Okay. And then if you look at the back page --

3 MR. LOPEZ: Go to the second-to-the-last page.

4 BY MR. LOPEZ:

5 Q. Do you see where your company's logo is there? That's the
6 company logo; right?

03:53:50

7 A. Yes.

8 Q. And if you look at page 6 of 20, I'm sorry, page eight of
9 20, do you know what that is?

10 A. It says Attachment B, Detailed Summary of Selected
11 Patients.

03:54:18

12 Q. These are about patients in the EVEREST study; right?

13 MR. NORTH: Objection, 602.

14 THE WITNESS: I've never seen this document before.
15 I don't know what they are, but I would assume that's what it
16 says.

03:54:29

17 BY MR. LOPEZ:

18 Q. But this is an official document sent from the medical
19 monitor of the EVEREST trial?

20 A. I don't know what it is, sir.

03:54:38

21 MR. LOPEZ: Your Honor, I'm going to offer 704 at
22 this time.

23 MR. NORTH: Objection, Your Honor. 901. It is not a
24 Bard document. 802, hearsay.

25 THE COURT: Sustained on hearsay grounds.

03:54:55

United States District Court

ROBERT M. CARR, JR. - Direct

1 MR. LOPEZ: It is a Bard document. 03:54:57

2 THE COURT: Sustained on hearsay grounds.

3 BY MR. LOPEZ:

4 Q. Were you ever advised, Mr. Carr, while you were -- while
5 the EVEREST study was going on that the medical monitor, 03:55:10
6 Dr. Kandarpa, suggested that that -- he suggested that the
7 study stop because of all of the complications that were
8 happening within the study?

9 A. No.

10 Q. Have you ever read anything that says that? 03:55:25

11 A. No.

12 Q. Were you aware that Dr. -- did anyone ever tell you that
13 Dr. Kandarpa suggested that because of what he saw in the
14 study, that the company should redesign the G2 filter?

15 A. No. 03:55:49

16 Q. I provided a number of documents to your counsel yesterday
17 or the day before that relate to the medical monitor
18 adjudication meeting minutes. Did you review those before you
19 came here today to see if they refresh your recollection about
20 whether or not you were aware of any of the information 03:56:12
21 contained within those meeting minutes?

22 A. No.

23 Q. Did you, as part of your work on the G2 filter, ask to
24 have done what is known as a caudal Push Test?

25 A. I believe so, yes. 03:56:35

United States District Court

ROBERT M. CARR, JR. - Direct

1 Q. Pardon me?

03:56:36

2 A. I believe so, yes.

3 Q. 1578, please. So before I move on to this, after the
4 results of the EVEREST study, didn't the results of the EVEREST
5 study, the number of tilts, the number of migrations, the
6 number of perforations, and the number of fractures confirm
7 what the signal that the company was getting just from the
8 adverse event reports that were coming in the first three or
9 four months that the device was on the market?

03:56:57

10 A. I'm not sure what you mean by "confirm."

03:57:20

11 Q. In other words, if the company was seeing caudal
12 migrations, tilts and fractures and sometimes in a combination
13 of two or more of those in the first three or four months it
14 was on the market, the EVEREST study confirmed those same types
15 of events, didn't they?

03:57:38

16 A. They are known complications and so all filters have all
17 of those events.

18 Q. I didn't ask you that. I asked you whether or not what
19 you were seeing in the adverse events that was causing concern
20 at the company and the concern that the device needed to be
21 redesigned, did you see further confirmation of that in the 83
22 patients that were in the EVEREST study, yes or no?

03:57:59

23 A. No.

24 Q. Did the EVEREST study give you a rate significantly higher
25 for tilt high immigration and perforation than what you were

03:58:19

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ROBERT M. CARR, JR. - Direct

1 seeing in the reports that were being voluntarily sent to your
2 company by doctors?

03:58:23

3 A. Yes.

4 Q. And did that confirm to you when you saw the 12 percent
5 and the 20 percent and those 18 percent complication rates for
6 those things that what you were getting in the field, in other
7 words from doctors, was a much smaller percentage of the
8 reality that was happening in patients?

03:58:37

9 A. No.

10 Q. Okay. So the EVEREST study was a controlled study that
11 had the complications that we've already seen; right?

03:58:55

12 A. Yes.

13 Q. Doesn't a clinical study where patients are actually being
14 monitored, doesn't that give you better data on rates than an
15 unknown underreporting and unknown lot of things about adverse
16 event reporting to the MAUDE database and to the company?

03:59:16

17 A. Yes.

18 Q. Okay.

19 MR. LOPEZ: And let's look at 1578.

20 BY MR. LOPEZ:

03:59:33

21 Q. So if there was any doubt that what was being reported to
22 the company in the three or four months was just the tip of the
23 iceberg, that problem got answered and resolved once you
24 started seeing the results in the EVEREST study; true?

25 A. Again, I don't know what you're referring to.

03:59:45

United States District Court

ROBERT M. CARR, JR. - Direct

1 Q. Well, tip of the iceberg means you're only seeing just a 03:59:47
2 small little percentage of what might actually be happening
3 with this product in patients. And what the EVEREST study did
4 was to show the company that what they actually were seeing --
5 that was actually causing them concern in the first three or 04:00:04
6 four months that this device was on the market was actually
7 borne out in much higher rates once the company did a clinical
8 trial; true?

9 A. I don't know the rates that you're referring to in the
10 beginning. I know there were four and three observations. The 04:00:18
11 data in the clinical trials stands on its own. I'm not sure of
12 the question.

13 Q. Okay. Let's look at 1578 and is this is Caudal Migration
14 Test Method Development and G2 Filter Resistance Test Report
15 that you're familiar with? 04:00:43

16 A. I don't know if it's the final one but that's what the
17 title says.

18 Q. Did you bring one that is different than the one that we
19 have on the screen right now?

20 A. Again, I didn't bring anything. 04:00:53

21 Q. You saw this before you testified?

22 A. If this is the final one?

23 Q. If there was a final one that wasn't this one, you have
24 access to it?

25 A. Me personally? It would be in our files. 04:01:07

United States District Court

ROBERT M. CARR, JR. - Direct

1 Q. When you got this, did you check it out to see if this was 04:01:10
2 not the final report?

3 A. I don't know what you mean by when I got it.

4 Q. Well, yesterday when it was shown to you.

5 A. I don't know that this was shown to me yesterday. 04:01:21

6 Q. All right. Let's look at this. So this is project 8049.
7 What is 8049?

8 A. The project number.

9 MR. LOPEZ: I would like to offer 1578 into evidence
10 at this time, Your Honor. 04:01:42

11 MR. NORTH: No objection.

12 THE COURT: 1578 is admitted.

13 (Exhibit Number 1578 was admitted into evidence.)

14 MR. LOPEZ: May I publish it to the jury?

15 THE COURT: Yes. 04:01:48

16 BY MR. LOPEZ:

17 Q. Okay. If you look at the bottom, it says date approved,
18 11-27-06?

19 A. Yes.

20 Q. Can we agree that this is a final report? 04:01:59

21 A. Usually it would have a signature page on it.

22 Q. First of all, tell the jury what is a caudal migration --
23 what this test report is?

24 A. Can you make it bigger so that I can read it? The
25 objective of the study was to evaluate multiple caudal 04:02:28

United States District Court

ROBERT M. CARR, JR. - Direct

1 migration resistance test methods and then use these test
2 methods to evaluate the caudal migration resistance of the G2
3 filter versus other commercially available filters.

4 Q. Okay. Is this the first time that the G2 has been
5 subjected to this type of test?

6 A. Maybe.

7 Q. You say maybe?

8 A. I did.

9 Q. Well, I mean, is there another test that you think might
10 exist that we didn't get?

11 A. No.

12 Q. Have you seen another test other than this one as it
13 relates to G2?

14 A. There might be some laboratory notebook stuff that was
15 done prior to this.

16 Q. The Recovery filter also experienced some issues with
17 caudal migration; true?

18 A. I don't recall that, no.

19 Q. And this device had caudal migration where we just saw a
20 document by March I think of 2006 it was determined to have an
21 unacceptable risk of caudal migration. Do you remember seeing
22 that?

23 A. I do because there was no control in place at the time to
24 mitigate it.

25 Q. Okay. Now we have a caudal Push Test that's done in --

United States District Court

ROBERT M. CARR, JR. - Direct

1 well, we know it's approved November of 2006 so sometime near
2 the end of 2006; correct?

3 A. It appears so, yes.

4 Q. And if you look at page seven of 21, you'll see that all
5 of the devices against which the G2 was going to be tested
6 against for caudal migration resistance; true?

7 A. Okay. Yes.

8 Q. There's the Simon Nitinol, Recovery, the Greenfield, and
9 then Tulip and OptEase, the top three being competitors of
10 Bard; right?

11 A. Yes.

12 Q. Let's go to page 11 of 21. And here are some of the
13 results of these tests.

14 MR. LOPEZ: Can you blow that up, Greg, the graph?

15 It's difficult to see but maybe we can -- actually, it's better
16 blown up.

17 BY MR. LOPEZ:

18 Q. So that if we look at this, we see that all of the devices
19 that were tested are on this graph; correct?

20 A. Yes.

21 Q. And the G2 is the diamond.

22 MR. LOPEZ: Can I actually do this, Your Honor,
23 circle it on this?

24 THE COURT: Can you do it?

25 MR. LOPEZ: I mean, is there a way for me to touch it

United States District Court

ROBERT M. CARR, JR. - Direct

1 or does the witness have to do it?

04:05:16

2 THE COURT: Traci, can you turn that on?

3 I think if you do it on the monitor to your left, it
4 might work.

5 COURTROOM DEPUTY: Yes, this one.

04:05:27

6 BY MR. LOPEZ:

7 Q. Okay. So the diamond is the G2; correct? Do you see
8 that?

9 A. The open diamond, yes.

10 Q. And then the Recovery -- I'll tell you what, I'm going to
11 let you circle where the Recovery is. I can't tell. It looks
12 like it's right above the diamond.

04:05:41

13 A. I think it's the one right above the diamond.

14 Q. Okay. Let me circle it.

15 And Simon Nitinol filter is this square right here;
16 right?

04:05:58

17 A. The open square, yes.

18 Q. And this depicts the average load, peak load for caudal
19 migration. Is it pretty clear that the G2 is lower than the
20 Recovery and the Simon Nitinol filter?

04:06:16

21 A. Yes.

22 Q. And it's lower than T, which is TRAPEASE, right, a
23 competitor?

24 A. It's lower than all but one.

25 Q. And it's lower than OptEase, another competitor; right?

04:06:29

United States District Court

ROBERT M. CARR, JR. - Direct

1 A. Yes.

04:06:32

2 Q. And if you look at the bottom of this page, it actually
3 gives you the values -- I'm sorry. Let's go to the next page,
4 page 12 of 21.

5 MR. LOPEZ: Can you highlight the first three? Just
6 do the whole table, Greg. That's fine.

04:06:55

7 BY MR. LOPEZ:

8 Q. And you see the G2, T for Tulip, the Simon Nitinol filter
9 and OptEase and do you see the values, the mean values --

10 A. I do.

04:07:09

11 Q. -- for caudal migration. I mean, all of these other
12 devices, at least with respect to this test, resist the caudal
13 migration at least almost ten times or more than the G2 filter;
14 correct?

15 A. Yes.

04:07:28

16 Q. And that was tested in a 15 millimeter cava and then a 21
17 millimeter cava and let's go to a 28 millimeter cava and you'll
18 see that in every one of these, the G2 filter was significantly
19 less resistant to caudal migration in this testing than any
20 other device that it was tested against; correct?

04:07:56

21 A. I've only seen the 15 so far.

22 Q. Pardon me?

23 A. The other ones have not come up yet. Yes.

24 Q. G2 21 -- let's just quickly show page 13, 21 millimeter.

25 A. Yes.

04:08:23

United States District Court

ROBERT M. CARR, JR. - Direct

1 Q. Do you see that? Not even close, right, in comparison to
2 others?

3 A. It's less, except for the Greenfield.

4 MR. LOPEZ: And if you go to page 17 of 21, show us
5 that top box, please.

6 Q. This test actually measured how far each one of these
7 devices would migrate in a caudal direction. Do you see that?

8 A. Yes.

9 Q. And that is that 11 centimeters?

10 A. I don't know.

11 Q. But the G2 was clearly outperformed by every other device
12 that it was tested against?

13 A. No.

14 Q. Except for which one?

15 A. Recovery and Greenfield.

16 Q. Well, wait a minute. The G2 migrated 11 and the Recovery
17 10 and the Greenfield 9.

18 A. There's no difference between those numbers statistically.

19 Q. Okay. But just on the numbers, the migration, the
20 distance of migration as recorded here, the mean, the G2 was
21 the highest?

22 A. Yes, but not statistically different.

23 MR. LOPEZ: Okay. Let's go to page 21 of 21, please.

24 BY MR. LOPEZ:

25 Q. They call this a Push Test; right?

ROBERT M. CARR, JR. - Direct

1 A. Of the tests that were developed, yes, they called it a
2 Push Test.

3 MR. LOPEZ: Can we have that first full paragraph,
4 Greg, highlighted. I'm sorry, not highlighted but blown up.

5 BY MR. LOPEZ:

6 Q. So the Push Test, which is the test that we're talking
7 about, was found to be the most accurate and consistent test
8 method and was best able to evaluate filter caudal migration
9 resistance while at the same time providing quantitative data;
10 correct?

11 A. That's what it says.

12 Q. In fact, it says it again in the last paragraph: In
13 conclusion, the paragraph just below this one:

14 In conclusion, the Push Test was the most successful
15 test method and should be used as the primary test method for
16 evaluating the caudal migration resistance of filters in the
17 future.

18 Correct?

19 A. That's what it says, yes.

20 Q. So you didn't find anything wrong with the test. It was a
21 good test. It was the kind of test that you thought even in
22 the future should be run on filters to see if there was a
23 problem at least on the bench with caudal migration?

24 A. The goal was to develop a good test, yes.

25 Q. And a test that you performed in the latter part of 2006?

United States District Court

ROBERT M. CARR, JR. - Direct

1 A. That's when this was developed.

04:11:45

2 Q. About six months before Sheri Booker got her G2 filter?

3 A. I don't know.

4 Q. You don't know when Sheri Booker, the plaintiff in this
5 case, got her G2 filter?

04:11:53

6 A. The date, no.

7 Q. Do you know what happened to her?

8 A. Generally.

9 Q. Tell us what you know about what happened to her.

10 MR. NORTH: Objection, 402.

04:12:04

11 THE COURT: Sustained.

12 BY MR. LOPEZ:

13 Q. Was Sheri Booker's doctor, her hospital or anyone else in
14 the medical community advised, number one, that even in the
15 bench testing, that your device was much, much worse than both
16 the Recovery filter and the Simon Nitinol filter?

04:12:18

17 A. No, because it wasn't much, much worse.

18 Q. Okay. And was Sheri Booker's doctors, anyone in the
19 medical community advised that in addition to this bench --

20 this caudal Push Test showing the G2 to be inferior to the
21 other devices it was tested against, that the company was still
22 trying to figure out how to redesign it to deal with caudal
23 migration?

04:12:40

24 A. First off, it wasn't inferior to all of the other filters.

25 And, no, they were not told.

04:12:56

United States District Court

ROBERT M. CARR, JR. - Direct

1 Q. Sir, do you agree that the Simon Nitinol filter is the 04:13:12
2 baseline predicate for safety and effectiveness for both the
3 Recovery and the G2?

4 A. The SNF is the predicate device for Recovery and Recovery
5 is the predicate device for G2 I believe. 04:13:28

6 Q. Okay. My question is a little different than that. Are
7 all three devices that are used -- I'm sorry. Was the Simon
8 Nitinol filter the baseline predicate device for both the
9 Recovery and the G2?

10 A. I think I answered that. Sorry. SNF was the -- one of 04:13:50
11 the predicate devices for Recovery. Greenfield was the other
12 one. And for G2, I believe Recovery was the predicate device.

13 Q. But in reality, regardless of what predicate device was
14 used for the G2, it needed to be substantially equivalent from
15 a safety and effectiveness standpoint as the Simon Nitinol 04:14:26
16 filter?

17 A. As the predicate device.

18 Q. Let's look at one more document, 703. I'm sorry, not 703.
19 5303, please. Sir, are you familiar with the
20 document that is in front of you right now? 04:15:48

21 A. Yes.

22 Q. G1A Recovery Filter Femoral System Design Verification and
23 Validation Report. How are you familiar with this?

24 A. It's the verification and validation report that was used
25 to support the G2 submission to the FDA. 04:16:08

United States District Court

ROBERT M. CARR, JR. - Direct

1 MR. LOPEZ: I would like to offer Trial Exhibit 5303
2 into evidence at this time.

04:16:16

3 MR. NORTH: No objection, Your Honor.

4 THE COURT: Admitted.

5 MR. LOPEZ: May I publish to the jury?

04:16:25

6 THE COURT: Yes.

7 (Exhibit Number 5303 was admitted into evidence.)

8 BY MR. LOPEZ:

9 Q. How is it you are familiar with this? Were you involved
10 in these actual studies directing people what to do or not do?

04:16:36

11 A. I was -- I don't know if I was the still in charge of
12 filters at the time, but I was generally aware of what was
13 going on, yes.

14 Q. Okay. Let's quickly go to page 13 of 20.

15 MR. LOPEZ: Greg, can you just bring up the top two
16 tables at the very top there? Right.

04:17:04

17 BY MR. LOPEZ:

18 Q. And, again, this test was being conducted for the purposes
19 of substantial equivalence to support the G2 clearance in the
20 510(k) process; right?

04:17:21

21 A. Yes.

22 Q. And acceptance criteria was G1A filter must have
23 equivalent or less variation as SNF; correct?

24 A. Yes.

25 Q. And then down below, G1A filter must be statistically

04:17:37

United States District Court

ROBERT M. CARR, JR. - Direct

1 equivalent or greater than SNF. Do you see that?

04:17:40

2 A. Yes, I do.

3 Q. And the G1A -- I think we mentioned this earlier but
4 that's actually the G2; right?

5 A. That's correct.

04:17:52

6 Q. And then go to the next page, please, going, 14 and the
7 first two again tables. One of the filter migration tests,
8 acceptance criteria. G1A filter must have equivalent or less
9 variation as SNF; correct?

10 A. Yes.

04:18:16

11 Q. Because the SNF was going to be the predicate device in
12 order to get clearance from 510(k) to be marketed; correct?

13 A. Yes.

14 Q. And then the next one, G1A must be statistically
15 equivalent or greater than SNF and that test failed. Do you
16 see that?

04:18:35

17 A. I do.

18 Q. And then as we go down through this document, we'll see
19 other areas where the G1A filter was at least the -- the
20 threshold was it was supposed to be statistically greater than
21 the SNF; right?

04:18:57

22 A. Equivalent to or greater and that was the initial
23 acceptance criteria.

24 Q. So we saw at least one of these tests had failed in that
25 acceptance criteria; right? We just showed that to the jury.

04:19:08

United States District Court

ROBERT M. CARR, JR. - Direct

1 A. Yes, and there's an explanation in the paragraph
2 following.

3 Q. Well, let's look at page 20 of 20. And the acceptance
4 criteria for purposes of filter migration was originally
5 migration resistance of G1A must be statistically equivalent to
6 or greater than that of the SNF filter; right?

7 A. Yes, same as before.

8 Q. And what happened was, there was a decision made that the
9 filter migration resistance would be changed to migration
10 resistance of G1A must be statistically greater than that of
11 the RNF filter in a 28 millimeter diameter simulated IVC.

12 A. That's correct.

13 THE COURT: Mr. Lopez, we're at 4:20 so we're going
14 to break at this point. We'll resume in the morning.

15 Ladies and gentlemen, we'll see you at 9 o'clock.
16 Thank you very much.

17 (Jury departs at 4:20.)

18 THE COURT: You can step down, sir.

19 Please be seated. Counsel, how have you allocated
20 the time for the depositions that were played today?

21 MS. HELM: Your Honor, we've met on it and 62 minutes
22 should be applied to the defendants.

23 THE COURT: Okay. Give me just a minute then.

24 All right. Counsel, as of the end of today,
25 plaintiffs have used 19 hours and 55 minutes; defendants have

United States District Court

ROBERT M. CARR, JR. - Direct

1 used 5 hours and 57 minutes.

04:23:20

2 I received this afternoon another deposition
3 designation with more than 30 exhibits in it. It's the
4 Sullivan deposition designation. Are you really planning to
5 play Sullivan? I trust you're going to play every one of the
6 deposition designations that I've spent hours reviewing. And
7 if that's not true, then I would really rather not keep getting
8 them until you really know you're going to use them. So my
9 question is, on Sullivan, are we really going to use Sullivan
10 and do I need to rule on the 31 objections in that deposition?

04:23:39

04:23:55

11 MR. O'CONNOR: I think we are planning on using
12 Sullivan, Your Honor.

13 THE COURT: That's not a very firm response, Mr.
14 O'Connor.

15 MR. O'CONNOR: Well, I mean, we have to look at our
16 time now but we plan to play him as a regional sales manager.

04:24:09

17 THE COURT: And so you are planning to use him?

18 MR. O'CONNOR: Yes.

19 THE COURT: How about the other 13 that I've ruled on
20 so far?

04:24:24

21 MR. O'CONNOR: Well, we'll have to take a look at
22 those.

23 MR. LOPEZ: I mean, we want to.

24 THE COURT: When do you think you want Sullivan?

25 I'll tell you I don't think I can get it to you until

04:24:44

United States District Court

ROBERT M. CARR, JR. - Direct

1 the weekend. I don't have time this evening, I don't have time 04:24:46
2 tomorrow night. I could probably look at it Friday night
3 maybe, sometime on Saturday but --

4 MR. LOPEZ: We're probably going to have to rest
5 before then, Your Honor. 04:24:58

6 THE COURT: Based on what you said, you're going to
7 rest tomorrow?

8 MR. LOPEZ: Pardon me?

9 THE COURT: I think you said earlier you're going to
10 rest tomorrow so what were you planning to do with Sullivan 04:25:06
11 when it came in today?

12 MR. LOPEZ: Play it tomorrow.

13 THE COURT: Well, I'm sorry. It's too late for me to
14 get you rulings today on Sullivan. If you want to read
15 portions, I can rule on objections as we read. 04:25:22

16 MR. LOPEZ: Maybe we'll do that.

17 THE COURT: But I think that's the alternative,
18 because we just ran out of time for me to get you anything
19 tonight.

20 Okay. So I wouldn't plan on doing Sullivan on the 04:25:38
21 weekend unless you let me know but if you want to read portions
22 of Sullivan tomorrow, make sure that you have a copy of the
23 deposition transcript for me to follow along and I'll listen to
24 objections as it's read and I'll rule as we go.

25 I will mention, by the way, you probably aren't 04:25:55

United States District Court

ROBERT M. CARR, JR. - Direct

1 surprised by this, Nancy told me that as the jurors were 04:25:57
2 leaving for lunch, a few of them turned to her and said,
3 "Please, no more video depositions." I said the jurors made a
4 plea to Nancy as they were leaving at the end of the morning
5 session, "Please, no more video depositions." I think they are 04:26:13
6 a little tired of watching them just something for you to
7 factor in.

8 All right. On the FDA warning letter, I think I do
9 need to get some submissions from you on what are the contents
10 and the dates of the complaint so that I can make a more 04:26:37
11 information decision. I assume this could be used in the
12 rebuttal case if the plaintiff decides to use it. But it's not
13 something that I think I am going to make an informed decision
14 on without knowing more about the nature of these complaints.

15 I will tell you I'm not persuaded by parts seven and 04:26:55
16 eight. Those seem to me to be pretty tangential. To me the
17 key issue is part three that talks about G2 compliance, but I
18 think I need to know more about those to really evaluate
19 relevance. So the question is, when and how do you want to
20 submit that to me? 04:27:13

21 MR. NORTH: We can have something by the close of
22 business tomorrow. We can have something Friday morning,
23 whatever the Court's schedule.

24 MS. REED ZAIC: Friday morning would be better. I'm
25 just thinking of the jury charge conference tomorrow. 04:27:26

United States District Court

ROBERT M. CARR, JR. - Direct

1 THE COURT: If it's reserved for the rebuttal, you
2 can even do it over the weekend. I don't want to press you
3 because you've got other things to do and your trial work, but
4 I want to get you the ruling in as timely a form as I can.

04:27:29

5 MR. LOPEZ: Maybe we can wait even during the defense
6 case, Your Honor, if it becomes relevant to cross or something
7 like that. That's fine with us.

04:27:46

8 THE COURT: Okay. So don't feel like you need to get
9 to it me Friday morning. Why don't you all talk and decide
10 when that ought to get to me and I'll be happy to look at it.

04:27:59

11 MS. REED ZAIC: Thank you, Your Honor.

12 THE COURT: We are talking about jury instructions
13 tomorrow at 4:30, so please be prepared for that and the
14 verdict form.

15 And on the question that you raised this morning
16 about overall timing, Mr. Lopez, I looked at the time we have
17 remaining. Before today we had used 20 hours, 20 hours and
18 four minutes. If we continue to get five hours and 40 minutes
19 a day, which we have been pretty much doing so far, then we
20 will reach 54 hours, which is the total of both sides, by the
21 close of trial next Wednesday.

04:28:10

22 If we then on Thursday, when I wanted to get it to
23 the jury, we could add four hours, we would get it to the jury
24 by 2:15, which I think would be as good as we could hope for.
25 That would give us four additional hours of trial time. I can

04:28:35

04:29:01

United States District Court

ROBERT M. CARR, JR. - Direct

1 give each side two hours.

04:29:05

2 Now, I recognize you're not going to use all of that.
3 It seems to me if we're going to give this jury time to
4 deliberate, that's about as good as we can do.

5 So what I would say is that we ought to -- you ought
6 to assume that you've got two more hours per side. So a total
7 of 29 rather than 27. I think we can meet that if we keep
8 going at five hours and 40 minutes per day and get the jury the
9 case by midafternoon on Thursday, which I think is about as
10 late as we can do, especially if we've got to then do some
11 punitive work potentially after the verdict.

04:29:21

04:29:40

12 Any thoughts or comments on that?

13 MR. LOPEZ: Well, if they don't need all theirs . . .

14 THE COURT: We can see how it's going next week. If
15 they finish the defense case with more time remaining than they
16 can use in closing then, yeah, I'll absolutely consider whether
17 that should be given to plaintiffs for rebuttal. But I
18 think -- I can't tell you now that we're going to do that
19 because they are entitled to use the time they have been
20 allotted.

04:29:56

04:30:11

21 MR. NORTH: Your Honor, I have one concern about
22 this. Giving the parties two hours each additionally per se
23 does not concern me. What concerns me is we've planned our
24 entire case based upon these limits and we have one witness
25 that we have worked out her availability that the only time she

04:30:32

United States District Court

ROBERT M. CARR, JR. - Direct

1 can be here is Friday. We're prepared to leave -- this Friday. 04:30:35
2 And we thought under the current allocation of hours, there was
3 no question but what we would have the case either tomorrow or
4 Friday.

5 THE COURT: Let me interrupt you. 04:30:50

6 I'm assuming you're resting before -- at least before
7 noon on Friday. Is that fair?

8 MR. LOPEZ: Our goal is by tomorrow.

9 THE COURT: I think you're going to be okay for
10 Friday. 04:31:02

11 MR. NORTH: Okay. I was just concerned if they
12 tacked two more hours onto their case-in-chief and we didn't
13 get the case until late Friday, we would be in trouble.

14 THE COURT: I'm assuming you're good still with the
15 estimate. You'll try to finish tomorrow even with the 04:31:13
16 additional two hours.

17 MR. O'CONNOR: If we need to pull over and they have
18 to get a witness on before we rest, we have no problem.

19 THE COURT: Okay. So I think we're good on that.

20 MR. NORTH: Okay. Thank you, Your Honor. 04:31:27

21 MR. LOPEZ: Do you have a hearing at 4:30?

22 THE COURT: I do but I've got some patient lawyers
23 sitting here in the courtroom. Go ahead and raise the last
24 issue.

25 MR. LOPEZ: I'm troubled by not being able to get in 04:31:39

United States District Court

ROBERT M. CARR, JR. - Direct

1 documents that are clearly notice documents to the company
2 about a lot of stuff that deals with their risks and the
3 benefits. I mean, you know, I mean, these are company
4 documents. They were produced to us by Bard as part of our
5 discovery that these were responses to their adverse events.
6 I've got these meeting minutes that have all of their adverse
7 events on them and I can't cross-examine any witnesses with it
8 unless I find out who it was that created the doggone chart.

9 I mean, I think under that -- because this is a party
10 document and it's really an admission by the company that it --
11 it's not hearsay or it's an exception because, you know, we're
12 offering it for notices. These are all notice documents to the
13 company about the frequency, severity, and quality of the
14 performance of their device while it was on the market.

15 THE COURT: Well, when you say you're offering it for
16 notice, you are also offering it for the truth of the matter
17 asserted. You're saying they learned this true information
18 about the problem with their filter so it's definitely being
19 offered for the truth of the matter asserted. I have to apply
20 the hearsay rules. 801(d)(2) would allow you to introduce it
21 if you can present evidence that the document was created by
22 somebody who was an agent for the company, authorized to act on
23 behalf of the company. You have to lay that foundation before
24 I can admit it under 801(d)(2) and that's not a surprise. That
25 has been a rule of evidence for the last 40 years.

United States District Court

ROBERT M. CARR, JR. - Direct

1 MR. LOPEZ: Well, I understand but the surprise to 04:33:21
2 me, it's attached to a memo from the president of the company.

3 THE COURT: You're not talking about meeting minutes.
4 You're switching to the last three pages of 4327. But as I
5 read that document, it says a rep said this, a doctor said 04:33:37
6 this, a marketing person said this. It's quoting people so
7 it's clearly a different level of hearsay than the main memo.
8 It's hearsay within hearsay and you've got to have an exception
9 for that second level of hearsay before it comes into evidence.
10 And I haven't heard one articulated yet. 04:34:00

11 MR. LOPEZ: All right. We'll get something to you
12 tomorrow morning.

13 THE COURT: I'll be happy to hear your argument at
14 that point but I understand what you're saying but the hearsay
15 rules apply and they haven't changed in a long time. 04:34:10

16 MR. LOPEZ: No. I know. I'm just thinking, you know,
17 under that section that I keep -- there's too many letters. It
18 looks like alphabet soup to me.

19 THE COURT: 801(d)(2).

20 MR. LOPEZ: Yes, that it should not be hearsay or 04:34:27
21 there's an exception to hearsay because it's -- the company is
22 on notice.

23 THE COURT: Well, if you can satisfy the requirements
24 of 801(d)(2), I'll admit the document but you have to satisfy
25 it. And the fact that they produced it doesn't satisfy it and 04:34:40

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1 that is one of the things that folks try to address in 04:34:45
2 discovery is to cover that ground or by subpoenaing a corporate
3 representative.

4 MR. LOPEZ: You know, yet we get to read medical
5 articles to the jury like -- 04:34:57

6 THE COURT: That's 803(18). That's a different
7 hearsay rule.

8 MR. NORTH: Your Honor, we can argue this tomorrow if
9 necessary but I just want the record clear. A lot of those
10 documents, those minutes, come from this third-party vendor and 04:35:06
11 they are not our company documents.

12 THE COURT: Well, if you want to argue it tomorrow
13 morning, I'll be happy to hear what you have to say, Mr. Lopez.

14 MR. LOPEZ: Okay. Thank you, Your Honor.

15 (Whereupon, these proceedings recessed at 4:35 p.m.) 04:35:19

16 * * * * *

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C E R T I F I C A T E

I, ELAINE M. CROPPER, do hereby certify that I am
duly appointed and qualified to act as Official Court Reporter
for the United States District Court for the District of
Arizona.

I FURTHER CERTIFY that the foregoing pages constitute
a full, true, and accurate transcript of all of that portion of
the proceedings contained herein, had in the above-entitled
cause on the date specified therein, and that said transcript
was prepared under my direction and control, and to the best of
my ability.

DATED at Phoenix, Arizona, this 21st day of March,
2018.

s/Elaine M. Cropper

Elaine M. Cropper, RDR, CRR, CCP

United States District Court